**National Institute for Health and Care Excellence**

**Single Technology Appraisal (STA)**

**Abatacept for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs**

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

**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 |
|---|---|---|---|
| Appropriateness | Bristol-Myers Squibb Pharmaceuticals Ltd | No comment | Thank you for your response. |
| | Novartis | Appropriate | Thank you for your response. |
| | AbbVie | No comments to add. | Thank you for your response. |
| | 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. Abatacept works in a different way to currently available treatments for psoriatic arthritis and, as such, this | Thank you for your response. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | | represents a new and unique possible option for patients. Therefore, it is our feeling that a NICE appraisal of this treatment is appropriate. | |
| | Psoriasis and Psoriatic Arthritis Alliance | It would be entirely appropriate to refer this topic, given the mode of action is different to other similar class agents, therefore providing further choice and targets. | Thank you for your response. |
| Wording | Bristol-Myers Squibb Pharmaceuticals Ltd | No comment | Thank you for your response. |
| | Novartis | Appropriate | Thank you for your response. |
| | AbbVie | No comments to add. | Thank you for your response. |
| | Psoriasis and Psoriatic Arthritis Alliance | As it does not have marketing authorisation, it would make sense to assume that it is likely to be used to treat patients within the pathway as other biologic agents, following non-biological DMARDs, unless it can be proven to be cost-effective, safe and effective at an early intervention point. | Thank you for your response. Since the scope consultation the marketing authorisation for abatacept for this indication has been granted. |
| Timing Issues | Bristol-Myers Squibb Pharmaceuticals Ltd | No comment | Thank you for your response. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | Novartis | No comment | Thank you for your response. |
| | AbbVie | No comments to add. | Thank you for your response. |
| | Psoriasis Association | It is our belief that this appraisal is needed, however the fact that abatacept is yet to receive UK Marketing Authorisation for psoriatic arthritis would mean that this is not yet urgent. | Thank you for your response. Since the scope consultation the marketing authorisation for abatacept for this indication has been granted. |
| | Psoriasis and Psoriatic Arthritis Alliance | I'm not sure it is particularly urgent for the general psoriatic patient population, unless they have exhausted all therapeutic options, in which case, another agent to try would be extremely urgent. | Thank you for your response. |
| Additional comments on the draft remit | Bristol-Myers Squibb Pharmaceuticals Ltd | None | Thank you for your response. |
| | Novartis | None | Thank you for your response. |
| | AbbVie | No additional comments | Thank you for your response. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | Psoriasis and Psoriatic Arthritis Alliance | Potentially the term 'active psoriatic arthritis', could be seen as a bit loose and open to interpretation, maybe moderate to severe or terminology that is similar to other NICE guidance might be more appropriate and aid positioning within the pathway. | Thank you for your response. Since the scope consultation the marketing authorisation for abatacept for this indication has been granted. The marketing authorisation states that abatacept is indicated for active psoriatic arthritis and the remit reflects this. |

**Comment 2: the draft scope**

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| Background information | Bristol-Myers Squibb Pharmaceuticals Ltd | No comment | Thank you for your response. |
| | Novartis | Appropriate | Thank you for your response. |
| | AbbVie | No comments to add. | Thank you for your response. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | Psoriasis Association | The aim of treatment of psoriatic arthritis would be to prevent damage to the joints and progression of the disease, as well as to suppress inflammation and manage skin symptoms. | The sentence 'the aim of treatment is to suppress joint, tendon and ligament inflammation, and to manage the skin symptoms of the disease' has been updated to 'the aim of treatment is to prevent damage to the joints and progression of the disease as well as to suppress inflammation and manage skin symptoms' |
| | Psoriasis and Psoriatic Arthritis Alliance | Fatigue is a real problem that is often not taken seriously, but has a profound effect on QoL and the ability to function effectively, it would be useful to recognise that symptom and feed that into the appraisal particularly if this agent improves that domain. | Thank you for your response. The background section is intended to provide a brief overview of disease and its management. Quality of life is an outcome in the scope and it is anticipated that factors affecting quality of life will be discussed during the appraisal. No |

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| | | | changes needed to the scope. |
| The technology/ intervention | Bristol-Myers Squibb Pharmaceuticals Ltd | The technology:<br>Abatacept (Orencia, Bristol-Myers Squibb) selectively inhibits the costimulatory pathway required for full activation of T lymphocytes1.<br>It can be administered by intravenous infusion1 and/or subcutaneously via a pre-filled syringe2 or pre-filled pen (ClickJect) 3.<br><br>The regulatory submission for abatacept in this indication specifies both the IV (phase II4) and SC (phase III5) mode of administration.<br><br>References –<br>1 – Orencia (abatacept) 250mg powder for concentrate for solution for infusion, Summary of Product Characteristics; Bristol-Myers Squibb. Available at www.medicines.org.uk<br>2 – Orencia (abatacept) 125mg solution for injection (pre-filled syringe), Summary of Product Characteristics; Bristol-Myers Squibb. Available at www.medicines.org.uk<br>3 – Orencia (abatacept) 125mg solution for injection (pre-filled pen), Summary of Product Characteristics; Bristol-Myers Squibb. Available at www.medicines.org.uk<br>4 - Mease P, Genovese MC, Gladstein G, et al. Abatacept in the treatment of patients with psoriatic arthritis: results of a six-month, multicenter, | Thank you for your response. Since the scope consultation the marketing authorisation for psoriatic arthritis has been granted. The Summary of Product Characteristics states that that abatacept should be administered intravenously for psoriatic arthritis. The administration method description has been updated. |

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| | | randomized, double-blind, placebo-controlled, phase II trial. Arthritis Rheum. 2011 Apr;63(4):939–948. [PubMed]<br>5 - Mease P, Gottlieb A, van der Heijde D, FitzGerald O, Johnsen A, Nys M, Banerjee S, Gladman D. Abatacept in the Treatment of Active Psoriatic Arthritis: 24-Week Results from a Phase III Study [abstract]. Arthritis Rheumatol. 2016; 68 (suppl 10). [Link] | |
| | Novartis | According to the summary of product characteristics for abatacept, it is available as both powder for solution for infusion and prefilled pen for injection. Please clarify if the intended mode of administration is intravenous as specified in the scope. | Thank you for your response. Since the scope consultation the marketing authorisation for psoriatic arthritis has been granted. The Summary of Product Characteristics states that that abatacept should be administered intravenously for psoriatic arthritis |
| | AbbVie | No comments to add. | Thank you for your response. |
| | Psoriasis and Psoriatic Arthritis Alliance | Appears to be reflective of the technology. | Thank you for your response. Since the scope consultation the marketing authorisation for psoriatic arthritis has been granted. The Summary of Product |

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| | | | Characteristics states that that abatacept should be administered intravenously for psoriatic arthritis |
| Population | Bristol-Myers Squibb Pharmaceuticals Ltd | No comment | Thank you for your response. |
| | Novartis | Appropriate | Thank you for your response. |
| | British Society for Rheumatology | The scope should consider data for the subgroup of people who have oligoarthritis | Thank you for your response. Abatacept will be appraised within its marketing authorisation. |
| | AbbVie | No comments to add. | Thank you for your response. |
| | Psoriasis and Psoriatic Arthritis Alliance | I think it needs to be very clear as to what is considered to be 'active psoriatic arthritis', would this include a single swollen joint such as a toe or finger, that has not responded to non-biological DMARDS? If, so that could potentially be a large group of patients. | Thank you for your response. Abatacept will be appraised within its marketing authorisation. The appraisal committee will consider active psoriatic |

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| | | | arthritis as defined in the clinical trials that underpinned the marketing authorisation. |
| Comparators | Bristol-Myers Squibb Pharmaceuticals Ltd | Please consider apremilast as a comparator in this section. BMS anticipates NICE guidance being published imminently. | Thank you for your comments. Apremilast has been added as a comparator. |
| | Novartis | There are on-going NICE technology appraisals of secukinumab, certolizumab and apremilast for psoriatic arthritis (ID579, ID1017). Based on the wording of the final NICE recommendations in these appraisals, these treatments should be included as comparators in all relevant populations defined in the scope.<br>Biosimilars should also be included as comparators. | Thank you for your comments. Apremilast has been added as a comparator. The technology appraisal guidance for secukinumab, certolizumab pegol and apremilast has been published since the scope consultation. The scope has been updated to reflect this.<br>The economic analysis section states “For the comparators the availability and cost of biosimilars should be |

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| | | | taken into consideration". |
| | British Society for Rheumatology | Apremilast (after failure of biologic dmards) should be considered by the scope as a comparator. The BSR is aware that apremilast is subject to ongoing appraisal. | Thank you for your comments. Apremilast has been added as a comparator. |
| | Merck Sharp & Dohme Limited | We feel that it has not been clarified why this TNF-α inhibitor has been considered for use after failure of one DMARD, when previous guidance (TA220 and TA199) recommends TNF-α inhibitor therapy after the failure of two DMARDs. The exception to this rule is ustekinumab (TA340), where it is recommended when treatment with a TNF-α is contraindicated, but would have otherwise been recommended. If a decision is made to increase the potential population, and expand the recommendation, then this should apply to all TNF-α inhibitors. | The comparator section in the scope is kept broad and inclusive so that it reflects the wording of the marketing authorisation in line with previous scopes for psoriatic arthritis. |
| | AbbVie | Since abatacept is still unlicensed in this indication, Abbvie is unclear as to the proposed positioning within the treatment pathway. Abbvie wishes to highlight that treatment delay in PSA is strongly related to worse overall outcomes and a delay to biologic use might not be in the patients' best interest. | Thank you for your comment. Since the scope consultation the marketing authorisation for abatacept for psoriatic arthritis has been granted. Abatacept will be appraised within its marketing authorisation. |

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| | Psoriasis Association | Apremilast (Otezla) should also be included as a comparator.<br><br>'Best supportive care' for most people would mean regression to a biologic or systemic treatment already tried that has not produced adequate results, or non-DMARD therapy that consists of symptom management (e.g. painkillers, NSAIDs, physiotherapy). For many, 'best supportive care' means sub-optimal or no disease-modifying treatment, leading to disease progression and poor outcomes. | Thank you for your comments. Apremilast has been added as a comparator.<br><br>The definition of best supportive care will be considered in more detail if the topic proceeds to full appraisal. |
| | Psoriasis and Psoriatic Arthritis Alliance | Definition of BSC, needs to be clearly defined. It would be useful to understand if that is the same as placebo within the trials. | The definition of best supportive care will be considered in more detail if the topic proceeds to full appraisal. |
| Outcomes | Bristol-Myers Squibb Pharmaceuticals Ltd | No comment | Thank you for your response. |
| | Novartis | Agree | Thank you for your response. |

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| | AbbVie | Abbvie believes that additional outcomes such as fatigue, WPAI and nail psoriasis indices should be included to reflect patient reported outcome measures more consistently. | Thank you for your response.<br>More specific outcomes may be considered as part of the overarching outcomes currently in the scope if this topic proceeds to full appraisal. |
| | Psoriasis Association | Skin psoriasis outcomes should also be considered, although this may fall within 'disease activity'. | Thank you for your Thank you for your response.<br>More specific outcomes may be considered as part of the overarching outcomes currently in the scope if this topic proceeds to full appraisal. |
| | Psoriasis and Psoriatic Arthritis Alliance | I think from a patient perspective, fatigue, improved sleep and reduced morning stiffness would be useful and important outcomes, particularly given this is a younger population of working age who need to be able to function and attend a place of work. | Thank you for your response.<br>More specific outcomes may be considered as part of the overarching outcomes currently in the scope if this topic |

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| | | | proceeds to full appraisal. |
| Economic analysis | Bristol-Myers Squibb Pharmaceuticals Ltd | No comment | Thank you for your response. |
| | Novartis | To facilitate validation of the economic analysis results with those accepted by NICE for comparator technologies, the economic analysis should reflect the model structure, assumptions and scenarios preferred by the NICE committee in recent NICE appraisals. | Thank you for your response.<br>This may be considered in more detail if the topic proceeds to full appraisal. |
| | AbbVie | For comparison with previously conducted technology appraisals it will be important to ensure analyses are conducted using the same assumptions on time horizon and discount rates. | Thank you for your response.<br>This may be considered in more detail if the topic proceeds to full appraisal. |
| | Psoriasis and Psoriatic Arthritis Alliance | No comments | Thank you for your response. |
| Equality and Diversity | Bristol-Myers Squibb | No comment | Thank you for your response. |

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| | Pharmaceuticals Ltd | | |
| | Novartis | No comment | Thank you for your response. |
| | AbbVie | No comments to add. | Thank you for your response. |
| | Psoriasis and Psoriatic Arthritis Alliance | Nothing to say on this. | Thank you for your response. |
| Other considerations | Bristol-Myers Squibb Pharmaceuticals Ltd | No comment | Thank you for your response. |
| | Novartis | No comment | Thank you for your response. |
| | AbbVie | No comments to add. | Thank you for your response. |
| | Psoriasis and Psoriatic Arthritis Alliance | If a group could be identified to be good responders to T cell blockers, ahead of other agents, that would appear to be useful consideration, instead of the current route of trying and failing a drug until a response. It certainly would improve cost-effectiveness. | Thank you for your response. |

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| Innovation | Bristol-Myers Squibb Pharmaceuticals Ltd | No comment | Thank you for your response. |
| | Novartis | No comment | Thank you for your response. |
| | Merck Sharp & Dohme Limited | We do not believe that abatacept is a step-change in the management of this condition, as there are other treatment options available with the same mechanism of action. | Thank you for your response. |
| | AbbVie | No comments to add. | Thank you for your response. |
| | Psoriasis Association | This treatment does not represent a step-change, but will offer an alternative treatment option within the somewhat limited pool available for people with psoriatic arthritis. | Thank you for your response. |
| | Psoriasis and Psoriatic Arthritis Alliance | Potentially a different target could be seen as innovative, but method of delivery is similar to other biologic agents and from a patient perspective, it's another IV or sub-cut injection so not likely to be seen as innovative from that point of view, unless frequency of dose is less often than current comparators, which it doesn't appear to be. | Thank you for your response.<br>This may be considered in more detail if the topic proceeds to full appraisal. |
| Questions for consultation | Bristol-Myers Squibb | No comment | Thank you for your response. |

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| | Pharmaceuticals Ltd | | |
| | Novartis | None | Thank you for your response. |
| | AbbVie | No comments to add. | Thank you for your response. |
| | Psoriasis and Psoriatic Arthritis Alliance | **How should best supportive care be defined?**<br>I suspect patients would be on some form of pain relief, this will include NSAIDs, steroid injections IM, inter-joint and probably some physiotherapy and exercise.<br><br>**Are the outcomes listed appropriate?**<br>I think fatigue and impact on sleep and morning stiffness is missing. These are major problems for people with psoriatic arthritis.<br><br>**Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom abatacept is expected to be more clinically effective and cost effective or other groups that should be examined separately?** | The definition of best supportive care will be considered in more detail if the topic proceeds to full appraisal.<br><br>More specific outcomes may be considered as part of the overarching outcomes currently in the scope if this topic proceeds to full appraisal.<br><br>Thank you for your comments. |

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| | | Those with skin psoriasis might be a group worth considering if it helps to improve that too.<br><br>**Where do you consider abatacept will fit into the existing NICE pathway, musculoskeletal conditions?**<br><br>Along side other biologic agents.<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 abatacept 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>**Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.**<br><br>I can't see that anyone is likely to be discriminated against, there is always a suggestion of needle and injection phobias around these drugs, but people | |

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| | | generally are very adaptable or find solutions to overcome such reluctance, if the treatment works with few adverse events.<br><br>**Do you consider abatacept 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><br>Different target could be seen as an innovation, but method of delivery may not.<br><br>**Do you consider that the use of abatacept can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?**<br><br>Societal benefit and the ability to be able work for this younger cohort, might not be fully captured<br><br>**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>Impact of disability and the cost that will have for those who will need financial support via the benefits system. | |
| Additional comments on the draft scope | Bristol-Myers Squibb Pharmaceuticals Ltd | None | Thank you for your response. |
| | Novartis | None | Thank you for your response. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | AbbVie | No additional comments | Thank you for your response. |
| | Psoriasis Association | Abatacept would fit alongside the approved biologics for psoriatic arthritis in the existing NICE pathway. | Thank you for your response. |
| | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for your response. |

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

Department of Health