National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Brodalumab for treating moderate to severe plaque psoriasis

Response to consultee and commentator comments on the draft remit and draft scope

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Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	Leo Pharma	Yes it would be appropriate to refer this topic to NICE for appraisal especially considering IL-17 cytokine has been identified, as having a critical role in the pathogenesis of psoriasis and .brodalumab has a different mode of action compared to the current IL-17 biologics i.e. it is the first IL-17 receptor blocker. Blocking IL-17 Receptor A on keratinocytes and immune cells has emerged as critical target for the treatment of psoriasis. *References were provided, but not replicated here.*	Comment noted.
	British Association of Dermatologists	Yes	Comment noted.
	Eli Lilly and Company	Yes	Comment noted.

Section	Consultee/ Commentator	Comments [sic]	Action
	Napp Pharmceuticals Limited	Yes	Comment noted.
	Novartis	We consider the proposed appraisal appropriate.	Comment noted.
	Psoriasis Association	Psoriasis is a condition that is very unique to each individual, and a treatment that works for one person may not necessarily work for another. Because of this, the Psoriasis Association is in favour of the widest possible variety of appropriate treatments being available to patients. Therefore, it is our feeling that a NICE appraisal of this treatment is appropriate.	Comment noted.
	UK Clinical Pharmacy Association	Yes it is very appropriate for brodalumab to be referred for appraisal now. It is the third IL-17 inhibitor to become available and so an appraisal is now needed	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	Given the many existing agents with NICE guidance it would be entirely appropriate to appraise brodalumab, although perhaps instead of an STA as part of an MTA with the view to understand what the pathway position is for this latest edition.	Thank you for your comment. NICE will appraise this technology using the single technology appraisal process.
Wording	Leo Pharma	Wording does reflect the issues.	Comment noted.
	British Association of Dermatologists	Yes	Comment noted.

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	Napp Pharmceuticals Limited	Yes	Comment noted.
	Novartis Pharmaceuticals	There is no clear definition of “moderate to severe plaque psoriasis”. Our understanding is that the Phase III studies of brodalumab in plaque psoriasis recruited patients with psoriasis area and-severity index (PASI) score of 12 or higher, a static physician’s global assessment (sPGA) score of 3 or higher and involvement of 10% or more of the body-surface area. The population for whom evidence on brodalumab clinical efficacy is available is therefore closely aligned to the populations included in studies of secukinumab and other biologic agents. Whilst secukinumab and other biologic agents have marketing authorisation for treatment of moderate to severe plaque psoriasis, NICE recommendations for these products refer to severe disease.	Comments noted. NICE will appraise brodalumab within its marketing authorisation.
	UK Clinical Pharmacy Association	Yes	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	As it doesn’t have a licence yet, I can’t see what else could be suggested.	Comment noted.
Timing Issues	Leo Pharma	The current IL-17A inhibitors available for treating moderate – severe Psoriasis all have the same mode of action (anti-IL17A antibody). Brodalumab on the other hand has a unique mode of action as an IL-17 receptor A blocker and thus it would be beneficial to give people with psoriasis access to this technology by providing guidance to the NHS as close as possible to marketing authorisation so clinicians and patients have an additional therapeutic option.	Comment noted.

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	British Association of Dermatologists	Should be assessed as soon as possible as innovative treatment	Comment noted.
	Napp Pharmceuticals Limited	Yes	Comment noted.
	Psoriasis Association	It is our belief that this appraisal is needed, however the fact that brodalumab is yet to receive UK Marketing Authorisation, and the fact that there are currently two other IL-17 antagonists available (secukinumab and ixekizumab) would mean that this is not yet urgent.	Comments noted.
	UK Clinical Pharmacy Association	I understand it has already received approval on Japan and an FDA decision is imminent. It is currently undergoing evaluation by the EMA. It would be helpful to have an NICE evaluation this year (2017)	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	No particular urgency, but given the availability of biosimilar, a review of their use and the impact of cost-effectivenes of all of the current therapies might be more urgent.	Comment noted.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background	Novartis Pharmaceuticals	The estimate that 90% of psoriasis patients have plaque psoriasis is perhaps a slight over-estimate. Raut et al. (2013) suggests a figure of 80%.	Thank you for your comments. 90% is an approximate estimate

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			for England, reported in the clinical guideline for psoriasis (CG153).
	UK Clinical Pharmacy Association	The effects of psoriasis on the skin are described but the background also needs to include additional information about the associated joint disease that affects a significant proportion of people with psoriasis (and can be disabling) and also the profound psycho-social burden imposed by the disease. Depression and suicidal ideation are not uncommon amongst people with moderate-severe psoriasis. It is important for these elements to be described because effective treatment might alleviate them. It would also be helpful to mention the nail disease that is often a part of psoriasis – again because effective treatment could affect this – and hitherto this has been very difficult to treat in any way.	Thanks for your comment. The background section has been amended to include "Psoriasis can be psychologically distressing to people". The background section of the scope is intended to provide a brief overview of the disease and its associated management.
	Psoriasis and Psoriatic Arthritis Alliance	Although not an indication for this agent, the fact that people can get psoriatic arthritis (20-30%) and some other agents are effective for both conditions, it might be useful to include as part of the text and also considered in the cost-effective analysis.	Thank you for your comment. The background section of the scope is intended to provide a brief overview of the disease and its associated management
The technology/intervention	Leo Pharma	The brand name for brodalumab is Kyntheum®. The last sentence of the technology description should read: *It has been studied in 3 phase III clinical trials compared with placebo or ustekinumab, in **adults** with moderate to severe plaque psoriasis.*	Thank you for your comment. The 'Technology' section of

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			the scope has been updated accordingly.
	British Association of Dermatologists	Yes	Comment noted
	Napp Pharmceuticals Limited	Yes	Comment noted
	UK Clinical Pharmacy Association	Yes	Comment noted
Population	Leo Pharma	Population is appropriate	Comment noted
	Napp Pharmceuticals Limited	Yes	Comment noted
	Novartis Pharmaceuticals	There is no clear definition of “moderate to severe plaque psoriasis”. Our understanding is that the Phase III studies of brodalumab in plaque psoriasis recruited patients with psoriasis area and-severity index (PASI) score of 12 or higher, a static physician’s global assessment (sPGA) score of 3 or higher and involvement of 10% or more of the body-surface area. The population for whom evidence on brodalumab clinical efficacy is available is therefore closely aligned to the populations included in studies of secukinumab and other biologic agents.[1-4] Whilst secukinumab and other biologic agents have marketing authorisation for treatment of moderate to severe plaque psoriasis,[5-9] NICE recommendations for these products refer to severe disease.[10-13]	Thank you for your comments. NICE will appraise brodalumab within its marketing authorisation.

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		References were provided, but not replicated here.	
	UK Clinical Pharmacy Association	It would be appropriate to consider those with psoriatic arthritis separately. Also – possibly – those with bad nail disease	Thank you for your comment. Brodalumab will be appraised within its marketing authorisation for psoriasis. Nail disease is captured in the 'Outcomes' section as being a symptom of psoriasis.
	Psoriasis and Psoriatic Arthritis Alliance	Yes, if that is the final licence indication.	Comment noted
Comparators	Leo Pharma	The comparator wording should be changed from: *For people with severe or very severe psoriasis for whom non-biologic systemic treatment or phototherapy is inadequately effective, not tolerated or contraindicated:* *to* *For people with severe psoriasis for whom non-biologic systemic treatment or phototherapy is inadequately effective, not tolerated or contraindicated* Tacrolimus is not licensed for Psoriasis or used within this patient group so should not be listed as a comparator.	Thank you for your comment. In order to keep the scope broad at this stage, infliximab has been retained as a comparator, which is recommended for very severe psoriasis. The scope has been updated to remove tacrolimus.

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		The limited use of infliximab in this indication and its recommendation for use only in very severe psoriasis makes it an unsuitable comparator (NICE TA134).	
	Eli Lilly	Tacrolimus is not licensed for psoriasis but is listed as a systemic non-biological comparator. Dimethyl fumarate is currently undergoing a NICE appraisal; therefore this may be a relevant comparator	The scope has been updated to remove tacrolimus. Dimethyl fumarate has been added to the list of comparators, subject to ongoing NICE appraisal.
	Napp Pharmceuticals	We suggest that it would be useful and consistent with the economic section to make this minor amendment (see italics below): • TNF-alpha inhibitors (etanercept, infliximab, adalimumab; *this includes biosimilar infliximab and etanercept).*	Thank you for your comment. Comparator technologies may include biosimilar products and the availability and cost of biosimilars should be taken into account. This is specified in the 'Economic analysis' section of the scope.
	Novartis Pharmaceuticals	We are not aware that tacrolimus is used systemically in the treatment of moderate to severe plaque psoriasis. Neither the oral nor topical formulations of tacrolimus are licensed for use in plaque psoriasis. In addition, there is no mention of any tacrolimus formulation in the British Association of Dermatologists' guidelines for biologic interventions for psoriasis.[15] We query whether PUVA (psoralen-ultraviolet A) should also be included as a potential comparator for patients in whom non-biological systemic treatment	Thank you for your comment. The scope has been updated to remove tacrolimus.

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		or phototherapy is suitable e.g. “Phototherapy, including with ultraviolet (UVB) radiation or psoralen-ultraviolet A (PUVA)”. Reference is made to people with “very severe” psoriasis. There is no clear definition of very severe psoriasis and we assume that the intention here is to consider a population aligned to the NICE guidance for infliximab (“very severe as defined by a total Psoriasis Area Severity Index (PASI) of 20 or more and a Dermatology Life Quality Index (DLQI) of more than 18”.[16] Biosimilars should also be included as potential comparators. *References were provided, but not replicated here.*	In previous consultations on psoriasis scopes, stakeholders advised that psoralen with ultraviolet A phototherapy (PUVA) is no longer routinely used for plaque psoriasis and therefore it has not been included as a comparator. No changes to the scope are required. Comparator technologies may include biosimilar products and the availability and cost of biosimilars should be taken into account. This is specified in the ‘Economic analysis’ section of the scope.
	Psoriasis Association	These are the standard treatments currently used in the NHS, although as a number of biosimilars are now available these may also need to be considered. The availability and costs of biosimilars should certainly be taken into account, however as individual treatments themselves. The British Association of Dermatologists recommends that patients are not 'switched'	Thank you for your comment. Comparator technologies may include biosimilar

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		from original biologic to its related biosimilar. Therefore, their availability and cost can only be considered an alternative at treatment commencement - not during treatment. Best supportive care for those in whom biologics are contraindicated or not tolerated is likely to be systemic non-biologics. However, one of the reasons to progress to biologics is contraindication and tolerability issues at the systemic non-biologic stage. Therefore, for a significant proportion of patients, best supportive care will mean topical therapy, possibly including an in-patient stay. This is based on what we hear anecdotally from our interactions with both patients and healthcare professionals. Fumaric acid esters is used off-licence in some UK centres and so this may need to be considered, however, it is not made available to all patients for whom it may be appropriate, and so could not be classified as 'standard'. Similarly, tacrolimus is noted in the draft scope, however in our experience this is used at all regularly in people with psoriasis.	products and the availability and cost of biosimilars should be taken into account. This is specified in the 'Economic analysis' section of the scope. Fumaric acid esters is considered as a relevant comparator. Tacrolimus has been removed from the scope.
	UK Clinical Pharmacy Association	Yes	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	Definition of BSC, needs to be very clear, in past appraisals this has had varying approaches. Including long-term inpatient stays, which given the current issues around dermatology bed availability might not be the case across England.	Thank you for your comments. The definition of best supportive care will be considered in more detail as part of the full appraisal.
	British Association of Dermatologists	Apremilast (as now approved by NICE) and fumaric acid esters (unlicensed but used in the psoriasis population with moderate severity) should both be considered in the comparator group.	Thank you for your comment. Both apremilast and fumaric

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		As indicated in the NICE guideline, ciclosporin should only be used for a maximum of a year. It is therefore only ever a relatively 'short-term' option. Psoriasis is a long-term condition and no treatments so far are 'curative'. Thus in any economic modelling, inclusion of ciclosporin is problematic. In addition, PUVA (i.e. phototherapy with psoralen), whilst effective, is no longer used routinely in people with psoriasis because of its propensity to cause skin cancer, particularly when followed by immunosuppression. In the NICE guideline certain groups are specified as 'DO NOT USE" populations; When considering PUVA this should only be when other options – including biologic therapies – have been offered and can't be used or are inappropriate. Established clinical practice is very much in line with CG153 – i.e. topicals for limited psoriasis only (not in the population being considered). Phototherapy – specifically UVB, and then systemic (non-biologic) therapy – particularly methotrexate. Where psoriatic arthritis is present, methotrexate may be used before phototherapy. Acitretin is not considered cost effective for patients who meet NICE criteria for biologic therapy and has limited utility due to poor tolerability and teratogenicity (a risk that persists for 3 years after treatment cessation). Ciclosporin is not used long term. In view of the high prevalence of metabolic syndrome (up to 40% in some studies), methotrexate is often contraindicated or is poorly tolerated due to abnormal LFTs. The population of patients with moderate disease (i.e. PASI<10) may still have significant disease with major impact (DLQI>10) and treatment options for this group are profoundly limited if methotrexate is ineffective or not tolerated, and ciclosporin cannot be used long term. Treatments used include acitretin, fumaric acid esters, apremilast, biologic drugs (but only if funded under IFR route). Systemic tacrolimus is not a suitable comparator.	acid esters are listed as comparators. The context within which comparators are used will be considered in detail in the full appraisal. The scope has been updated to remove tacrolimus.

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Outcomes	Leo Pharma	We agree with the outcomes that are being considered	Comment noted.
	Abbvie	Yes, with the added suggestion to consider joint outcomes. In addition, all adverse events linked with the treatment/comparators need to be reported, above all data on depression, suicide ideation and IBD flare.	Thank you for your comment. More specific outcomes can be considered under the broad scope outcomes, as part of the full appraisal. The background section has been amended to include “Psoriasis can be psychologically distressing to people“

	British Association of Dermatologists	Additional outcomes that should be considered includes:
		• Other high-impact and difficult-to-treat sites:
		  ○ Face
		  ○ Scalp
		  ○ Palms
		  ○ Soles
		  ○ Flexures
		  ○ Genitals
		• Injection site reactions
		• Mood
			Thank you for your comment. More specific outcomes can be considered under the broad scope outcomes, as part of the full appraisal.

	Eli Lilly	The potential for suicidal ideation is an outcome that should also be considered.	Thank you for your comment. More specific outcomes can be considered under the

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			broad scope outcomes, as part of the full appraisal. The background section has been amended to include “Psoriasis can be psychologically distressing to people“
	Napp Pharmceuticals	Yes	Comment noted
	Novartis Pharmaceuticals	In general the outcomes specified are appropriate. We note that consideration of brodalumab’s benefits in treating psoriasis symptoms on the face, scalp and nails would require studies adequately powered to detect statistically significant differences between interventions on these outcomes. In addition, given the short-term nature of most clinical studies in psoriasis, we consider it unlikely that adequate data to support mortality endpoints will be available.	Comment noted
	Psoriasis Association	Yes. As health-related quality of life (DLQI) and psoriasis area and severity (PASI) scoring is required to ascertain appropriateness to progress through the psoriasis treament pathway on to biologic treatments, it is essential that both of these outcomes are considered of comparable importance when assessing the treatment concerned. The other outcomes listed related to rate of response, maintenance of response, adverse effects and mortality, as well as consideration of the non-skin aspects of psoriasis (nails, joints, etc) are also of utmost importance. Is there a reason why psoriasis on the torso, limbs, and flexural psoriasis are not included in the outcome measures alongside ‘psoriasis symptoms on the	Thank you for your comment. The outcome section of the scope has been revised to include both PASI and DLQI.

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		face, scalp and nails'? Plaque psoriasis – which this treatment is intended for – can occur all over the body, not just on the face/scalp.	
	UK Clinical Pharmacy Association	It would be helpful to have some measure of psycho –social well-being – I am not sure if this is automatically captured in the HRQoL Given that a question mark has been raised over the possibility of 'suicidality' with brodalumab there needs to be some way of capturing this too. Also- effects on joint disease	Thank you for your comment. More specific outcomes can be considered under the broad scope outcomes, as part of the full appraisal. The background section has been amended to include "Psoriasis can be psychologically distressing to people"
	Psoriasis and Psoriatic Arthritis Alliance	Severity as measured by PASI should be looking at a higher threshold of gain of PASI90 and clearance as being where these newer agents should be seen as improving care, not just adding to the range of availability and reaching PASI75, which is 75% improvement from base	Thank you for your comment. The outcome section of the scope has been revised to include PASI. More specific outcomes can be considered under the broad scope outcomes, as part of the full appraisal.
Economic analysis	Leo Pharma	An economic analysis that adheres to the requirements of the NICE reference case will be submitted. The time horizon will depend on the assumptions used in the model, but will be sufficiently long to capture important differences between comparators.	Comment noted.

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	Napp Pharmceuticals	An attempt should be made to include the true acquisition price (tender price) for biosimilars as well as the published list price. When using the tender price it may be necessary to carry use a sensitivity analysis based on discounted NHS prices at 5 or 10% intervals as tender prices are confidential.	Comment noted. Comparator technologies may include biosimilar products and the availability and cost of biosimilars should be taken into account. This is specified in the 'Economic analysis' section of the scope.
	Psoriasis Association	The availability and costs of biosimilars should certainly be taken into account, however as individual treatments themselves. The British Association of Dermatologists recommends that patients are not 'switched' from original biologic to its related biosimilar.Therefore, their availability and cost can only be considered an alternative at treatment commencement - not during treatment.	Comment noted. Comparator technologies may include biosimilar products and the availability and cost of biosimilars should be taken into account. This is specified in the 'Economic analysis' section of the scope.
	UK Clinical Pharmacy Association	Psoriasis is chronic relapsing and remitting disease – so it would be helpful to have some modelling to evaluate treatment over several years I am not sure whether dose escalation is an issue with this class of drugs as it is with the anti-tnfs but this could be an important consideration over long-term treatment (years)	Thank you for your comment. The 'Economic analysis' section specify that the time horizon should be sufficiently long to

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			reflect any differences in costs or outcomes between the technologies being compared.
Equality and Diversity	Leo Pharma	No additional comments	Comment noted.
Innovation	British Association of Dermatologists	The technology is innovative - it is the first biologic that specifically targets IL-17 receptor A on keratinocytes and immune cells. In addition brodalumab has been shown in clinical trials to deliver PASI 100 (complete clearance from moderate to severe psoriasis symptoms) in approximately 40% of patients at week 12 increasing to over 50% of patients by week 52[2] – this is a step change in outcomes compared with the anti-TNFs and IL-23s which are still the main treatments used in this population. Worth noting that whilst QALYs can be used to measure the health gains of treating psoriasis, however the preferred instrument for measuring utility and QALYs in trials, the EQ-5D, lacks sensitivity to detect changes in QOL associated with treatment of non-fatal skin diseases. *References were provided, but not replicated here.*	Comments noted. Innovation will be considered in more detail as part of the full appraisal.
	British Association of Dermatologists	Yes – inhibitors of the IL17 pathway are a major step change in terms of ability to achieve clearance of disease (PASI90). Genetic and immunopathogenic studies strongly implicate the IL17 pathway to be of major relevance in psoriasis (and ps arthritis). Yes Neither the DLQI – the commonly used tool for impact in skin disease, or the EQ5D – encompass distress or low mood. These are extremely common	Comments noted. Innovation will be considered in more detail as part of the full appraisal.

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		in people with moderate-to-severe psoriasis and are known to improve with disease control.	
	Napp Pharmceuticals	*Do you consider the technology 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)?* No but it may be a useful 2nd or 3rd line treatment after other anti-TNFs *Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* No	Comments noted. Innovation will be considered in more detail as part of the full appraisal.
	Psoriasis Association	As there are currently two available IL-17 antagonists (secukinumab and ixekizumab, subject to NICE decision for the latter), brodalumab would not be considered innovative. However, as previously mentioned, psoriasis patients are all unique in their response to treatment, and what works for one will not necessarily work for another. Therefore, having an additional available treatment could make the difference for those who have found none yet to be successful.	Comments noted. Innovation will be considered in more detail as part of the full appraisal.
	UK Clinical Pharmacy Association	The IL-17 inhibitors as a group (secukinumab, ixekizumab and brodalumab) represent a step change in the management of psoriasis. It is important to understand the effectiveness of brodalumab in relation to the others in this group.	Comments noted. Innovation will be considered in more detail as part of the full appraisal.
	Psoriasis and Psoriatic Arthritis Alliance	Not particularly, inclusion of IL-25 signalling pathway is different, Mode of delivery is as other agents.	Comments noted. Innovation will be considered in more detail as part of the full appraisal.

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Other considerations	Novartis Pharmaceuticals	See comments above on remit wording, population and comparators in relation to the lack of clear definitions for moderate and severe psoriasis.	Comments noted.
	UK Clinical Pharmacy Association	It will be important to understand whether there is an optimal sequence for the use of biological therapies and whether brodalumab is interchangeable with other IL-17 inhibitor or not.	Thank you for your comments. The purpose of this appraisal will be to appraise brodalumab within its marketing authorisation.
	Psoriasis and Psoriatic Arthritis Alliance	Benefit to those with psoriatic arthritis. The recent FDA box warnings for suicidal ideation may need to be considered for a UK population.	Thank you for your comment. The background section has been amended to include “Psoriasis can be psychologically distressing to people“. More specific outcomes can be considered under the broad scope outcomes, as part of the full appraisal.
Questions for consultation	Leo Pharma	Re the suitability of this technology for an ATA: [redacted]	Comment noted.

Section	Consultee/ Commentator	Comments [sic]	Action
		• [redacted] • [redacted] • [redacted] [redacted]	
	Napp Pharmceuticals	*Have all relevant comparators for brodalumab been included in the scope?* Yes, it should be made clear that biosimilars of etanercept and infliximab are include in the Comparator section. *Which treatments are considered to be established clinical practice in the NHS for moderate to severe psoriasis?* Those identified in the scope *Are the subgroups suggested in 'other considerations appropriate?* Yes *Are there any other subgroups of people in whom brodalumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?* None *Where do you consider brodalumab will fit into the existing NICE pathway?* After TNF-alpha inhibitors have been used.	Comment noted. Comparator technologies may include biosimilar products and the availability and cost of biosimilars should be taken into account. This is specified in the 'Economic analysis' section of the scope.

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	Novartis Pharmaceuticals	*Have all relevant comparators for brodalumab been included in the scope? Which treatments are considered to be established clinical practice in the NHS for moderate to severe psoriasis?* Novartis: See comments above on "Comparators" *Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom brodalumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?* Novartis: Nothing further to add beyond comment that moderate and severe psoriasis are poorly defined. *Where do you consider brodalumab will fit into the existing NICE pathway?* Novartis: We would expect brodalumab to be positioned alongside the other biologics recommended by NICE for treating severe, or very severe, psoriasis. *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.* Novartis: No comment. *Do you consider brodalumab 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)?* Novartis: Two IL-17A inhibitors are already licensed for the treatment of chronic plaque psoriasis; NICE has recommended secukinumab and guidance for ixekizumab is in development. As the third IL-17A inhibitor to market, we do not consider brodalumab to represent an innovative treatment option.	Comments noted.

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		Do you consider that the use of brodalumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? Novartis: No comment. *We welcome comments on the appropriateness and suitability of considering the new ATA process for appraising this topic.* Novartis: Brodalumab may be suitable for the ATA process provided there is evidence to support health benefits that are similar or greater to those of secukinumab and the other biologic therapies, at a similar or lower cost.	
	Psoriasis Association	We would predict that brodalumab would fit into the existing NICE pathway at the same point as other biologic therapies for psoriasis. In particular, it is likely to sit alongside its fellow IL-17 antagonists, secukinumab and ixekizumab (subject to ongoing NICE appraisal).	Comments noted.
	Psoriasis and Psoriatic Arthritis Alliance	*Have all relevant comparators for brodalumab been included in the scope?* Looks complete. *Which treatments are considered to be established clinical practice in the NHS for moderate to severe psoriasis?* Adalimumab appears to be the most commonly first choice following conventional DMARDs *Are the subgroups suggested in 'other considerations appropriate?* I think although sequences is appropriate some flexibility for prescribers, based on individual patient need should be allowed. *Are there any other subgroups of people in whom brodalumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?* If it is shown to work in those with psoriatic arthritis, that could be a consideration.	Comments noted.

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		Where do you consider brodalumab will fit into the existing NICE pathway? Currently as with other agents following conventional DMARDs, (3rd line), but if the cost of the drugs were significantly lower and given the amount of safety data that has been collected, I can't see any reason why these types of drugs in the future couldn't be considered 2nd line or even 1st line in appropriate individuals. *Do you consider brodalumab 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)?* No not really. *Do you consider that the use of brodalumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* No, as long as the impact of the full disease utilities are captured.	
Any additional comments on the draft scope	Leo Pharma	*Where do you consider brodalumab will fit into the existing NICE pathway?* Brodalumab should be an alternative first line option within the systemic biological therapy section of the NICE psoriasis pathway.	Comments noted.
	Eli Lilly	Although brodalumab targets the IL-17 pathway, its mode of action is significantly different to secukinumab and ixekizumab and as such, it may not be suitable for the abbreviated technology appraisal process.	Thanks for your comment.
	Psoriasis Association	There were concerns raised following Phase III trials of brodalumab surrounding depression and suicidality. This technology appraisal may offer an opportunity to consider the evidence for this further.	Thanks for your comment. The background section has

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			been amended with the inclusion of additional symptoms.
	UK Clinical Pharmacy Association	The impact of obesity on response may need to be considered – whether obese individuals respond less well and/or need a bigger dose.	Thank you for your comments.

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

Janssen
MSD
Pfizer
Department of Heath