National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Abrocitinib for treating moderate to severe atopic dermatitis in people aged 12 and over ID3768

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Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	Pfizer	Yes [it is appropriate to refer this topic to NICE for appraisal].	Thank you for your comment. No action required.
	National Eczema Society	Yes, it would be appropriate to refer this topic to NICE for appraisal.	Thank you for your comment. No action required.
	Eczema Outreach Support	No comments	Thank you. No action required.
Wording	Pfizer	Since the marketing authorisation process is still ongoing, please change 'To appraise the clinical and cost effectiveness of abrocitinib within its marketing authorisation for moderate to severe atopic dermatitis in people aged 12 and over.' to 'To appraise the clinical and cost effectiveness of abrocitinib within its proposed marketing authorisation for moderate to severe atopic dermatitis in people aged 12 and over.'	Thank you for your comment. It is not standard wording for NICE scopes to use "proposed" in this way. The remit reflects the anticipated marketing authorisation and

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			clinical evidence base for abrocitinib, and the referral to NICE from DHSC for this appraisal. It is also consistent with an ongoing NICE appraisal in this indication (ID3733). Therefore, no changes have been made to the scope.
	National Eczema Society	Yes, the wording of the remit reflects the issue(s) of clinical and cost effectiveness about this technology.	Thank you for your comment. No action required.
	Eczema Outreach Support	No comments	Thank you. No action required.
Timing Issues	Pfizer	No comment	Thank you. No action required.
	National Eczema Society	N/A	Thank you. No action required.
	Eczema Outreach Support	Urgent as effective eczema treatments for the moderate/severe form of the condition are still limited.	Thank you for your comment. NICE aims to publish guidance as soon as possible after the company receives the marketing

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			authorisation and introduces the technology in the UK. NICE has scheduled this topic into its work programme.
Additional comments on the draft remit	Pfizer	No comments	Thank you. No action required.
	National Eczema Society	N/A	Thank you. No action required.
	Eczema Outreach Support	No comments	Thank you. No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Pfizer	First paragraph Please change *'Severe eczema can be physically disabling or incapacitating and can cause anxiety or depression'* to *'Moderate to severe eczema can be physically disabling or incapacitating and can cause anxiety or depression'* Supporting reference:	Thank you for your comment. The background section has been updated with the proposed changes. The statement about alitretinoin has been retained because alitretinoin is included as a potentially relevant

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		Simpson *et al.*, 2016 Patient burden of moderate to severe atopic dermatitis (AD): Insights from a phase 2b clinical trial of dupilumab in adults. Journal of the American Academy of Dermatology, Volume 74, Issue 3, 2016 Second paragraph No change Third paragraph The scoping document refers to tacrolimus ointment which is a calcineurin inhibitor recommended by NICE for the *'treatment of moderate to severe atopic dermatitis that has not been adequately controlled by use of topical steroids at the maximum strength and potency or where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy (TA82).'* For completeness please change to *'tacrolimus ointment (calciceurin inhibitor) is recommended by NICE as an option for second-line treatment of moderate to severe atopic eczema in adults and children aged 2 years and older that has not been controlled by topical corticosteroids at the maximum strength and potency, or where there is a serious risk of important adverse effects from further topical corticosteroid use, particular irreversible skin atrophy (TA82)'* Further please add that *'pimecrolimus (calcineurin inhibitor) is recommended as an option for the second-line treatment of moderate atopic dermatitis on the face and neck in children aged 2 to 16 years that has not been adequately controlled by use of topical steroids at the*	comparator in the scope.

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		maximum strength and potency or where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy (TA82)' Please also remove the reference to alitretinoin as this is not relevant to this appraisal as per out comments within the comparator section of our response below. <u>Fourth paragraph</u> Please replace *'moderate to severe dermatitis'* with *'moderate to severe atopic dermatitis'* in the first sentence. Please replace *'treated with stronger oral medications such as oral steroids, systemic immunosuppressants (azathioprine, ciclosporin, mycophenolate mofetil, methotrexate and dupilumab)'* with *'treated with stronger medications such as oral steroids, systemic immunosuppressants (azathioprine, ciclosporin, mycophenolate mofetil, methotrexate) and dupilumab'* Please remove the wording *'this option is not usually recommended for children'* in relation to use of phototherapy and photochemotherapy (psoralen–ultraviolet A; PUVA). Although reference 3 (British Association of Dermatologists. Atopic Eczema 2020) supports this statement, it is unclear what ages are covered under the term *'children.'* We would argue this does not relate to those aged >12 years (i.e., for adolescents and adults) which is the relevant population for the appraisal of abrocitinib.	

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		• The international Eczema Council recommends the use of phototherapy as a second-line or adjuvant therapy in patients with moderate-to-severe atopic dermatitis, especially in adults and older children. [Supporting reference: Simpson *et al.*, 2017 When does atopic dermatitis warrant systemic therapy? Recommendations from an expert panel of the International Eczema Council. Journal of the American Academy of Dermatology, Volume 77, Issue 4, 2017] • Further we have sought input from clinical experts who have confirmed that phototherapy is used for the treatment of moderate and severe atopic dermatitis in both adolescents and adults. Fifth paragraph No comment	
	National Eczema Society	The background information appears to be accurate and complete.	Thank you for your comment. No action required.
	Eczema Outreach Support	"Severe eczema can be physically disabling or incapacitating and can cause anxiety or depression." This is incomplete. Need to include the psycho-social burden of uncontrolled eczema on patients, families and society: Eczema is a complex disease shaped by genetic, immunologic and environmental factors, which makes its management unique to each individual and based on a long process of trial and error.	Thank you for your comment. The background section has been updated to reflect the impact of the disease on families and carers.

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		There is no cure for eczema, only management of symptoms. **Impact on adolescents:** Eczema is often misunderstood and thought of as just a bit of itchy skin. For an adolescent with severe eczema the reality is very different; it includes: recurrent infections, hospital admissions, enduring treatments such as 'wet wrapping' and immune-suppressants, missing school, not being able to take part in normal youth activities because their skin will flare, sleepless nights and pain from broken itchy skin. Indeed, research shows that eczema impacts on their education, relationships, social life and the family as a whole. Because eczema has a substantial and long-term negative effect on people's ability to carry out normal daily tasks, it is recognised as a disability under the Equality Act 2010. **Impact on carers:** The parents/carers spend hours daily supporting their adolescent in treating their skin with topical treatments, immuno-suppressants, UV treatments or hospital admissions. On top of this, the whole family deals with sleepless nights and the stress of the constant itching & scratching; the unpredictable flares are proven to increase the risk of anxiety and depression, especially in mothers. Over a quarter of parents caring for a child with moderate and severe eczema have to miss time at work. Some cannot work at all.	

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		Parents of children with eczema describe feelings of guilt, exhaustion, frustration and helplessness. Social life and familial relationships can be affected along with parenting behaviour. Finally, studies show that low-income families who may have minimal social support mechanisms suffer more, worsening health inequalities. In summary, uncontrolled eczema has a huge psycho-social impact on patients, their families and society.	
The technology/ intervention	Pfizer	<u>First paragraph</u> No comment <u>Second paragraph</u> This is not accurate given that: • several of the studies for abrocitinib do not allow rescue medications • one study includes an active comparator (dupilumab) • all studies included patients who had an inadequate response or intolerance to topical treatments or were candidates for systemic treatments Please replace paragraph with the following text:	Thank you for your comment. The second paragraph has been corrected. This is not intended to be a comprehensive summary of the clinical evidence base; rather, it is intended to make clear that there are several trials and indicate what comparisons and populations those trials include. Therefore, this section has been kept brief, rather than using the suggested comprehensive bullet points.

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		Abrocitinib does not currently have a marketing authorisation in the UK for atopic dermatitis. It has been studied in clinical trials: • *As a monotherapy compared with placebo in people aged 12 years and over with moderate to severe chronic atopic dermatitis. The trials included people who had a documented history (within 6 months of the screening visit) of inadequate response to treatment with medicated topical therapy given for at least 4 weeks, or for whom topical treatments were otherwise medically inadvisable, or required systemic therapies to control their disease.* • *In combination with medicated topical therapy compared with dupilumab and placebo in adults with moderate to severe atopic dermatitis. The trial included people who had a documented history (within 6 months of the screening visit) of inadequate response to treatment with medicated topical therapy given for at least 4 weeks, or who required systemic therapies for control of their disease.* • *In combination with medicated topical therapy compared with placebo in people aged 12-17 years with moderate to severe atopic dermatitis. The trial included people who had a documented history (within 6 months of the screening visit) of inadequate response to treatment with medicated topical therapy given for at least 4 weeks, or who required systemic therapies for control of their disease.*	
	National Eczema Society	Yes, as far as we are aware [the description of the technology is accurate].	Thank you for your comment. No action required.

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	Eczema Outreach Support	No comments	Thank you. No action required.
Population	Pfizer	No comment	Thank you. No action required.
	National Eczema Society	Yes, the population is defined appropriately. We don't think there are groups within this population that should be considered separately.	Thank you for your comment. No action required.
	Eczema Outreach Support	Adolescents should be considered a special subgroup, especially in regards to the risks of poor compliance; this is important when assessing the feasibility of the treatment method and frequency.	Thank you for your comment. NICE does not routinely use age to define subgroup analyses. In previous atopic dermatitis scopes, the appraisal has either looked at adults only, people aged 12-17 only, or all people aged 12 or over, based on the anticipated marketing authorisation and clinical trial evidence. Therefore, no change has been made to the scope.

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Comparators	Pfizer	There are several comparators that are **not** relevant to the decision problem, as was argued and accepted in the dupilumab appraisal (TA534). Phototherapy • Typically used earlier in the treatment pathway than the proposed positioning for abrocitinib. As described above, the International Eczema Council recommended use of phototherapy after the failure of topical therapies and before the use of immunosuppressants. • Short-term treatment option to control symptoms; it would not be used as a long-term treatment option for atopic dermatitis due to the potential increased risk of skin cancer. • Not available widely and only in specific centres Supporting reference: Simpson *et al.*, 2017 When does atopic dermatitis warrant systemic therapy? Recommendations from an expert panel of the International Eczema Council. Journal of the American Academy of Dermatology, Volume 77, Issue 4, 2017 Oral corticosteroids • Short-term treatment option to control symptoms; it would not be used as a long-term treatment option for atopic dermatitis. European guidelines state that courses of systemic steroids should not exceed 2 weeks due to long term side effects.	Thank you for your comment. The potential comparators listed in the scope represent treatments used to treat moderate to severe atopic dermatitis in NHS clinical practice after topical corticosteroids or topical calcineurin inhibitors. These comparators are consistent with previous scopes for moderate to severe atopic dermatitis. The scope is inclusive of all potentially relevant comparators and the appraisal committee will determine the most appropriate comparators for decision making. However, in line with the final scope for TA681, oral corticosteroids have been removed from the scope.

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		Supporting references: Wollenburg *et al.*, 2016. European Task Force on Atopic Dermatitis/EADV Eczema Task Force. ETFAD/EADV Eczema task force 2015 position paper on diagnosis and treatment of atopic dermatitis in adult and paediatric patients. Journal of European Academy of Dermatology and Venereology. Volume 20, Issue 5, 2016. Wollenburg *et al.*, 2018. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part II. Journal of European Academy of Dermatology and Venereology. Volume 32, Issue 6, 2018 Alitretinoin • Alitretinoin is indicated and recommended by NICE (TA177) for the treatment of adults with severe chronic hand eczema that has not responded to potent topical corticosteroids. Atopic dermatitis affecting the hands and chronic hand eczema are not synonymous. Atopic dermatitis is a multifaceted, chronic relapsing inflammatory skin condition that is commonly associated with other atopic manifestations. It affects typical anatomical sites at different ages. While most children and adults experience flexural involvement, some adult patients display involvement of the face, hands and feet. Chronic hand eczema, defined as a hand eczema lasting for longer than 3 months or relapsing 2 or more times per time, is a distinct type of dermatitis that develops on the hands and wrists and is commonly related to contact allergies as well as domestic and occupational irritant exposures. Therefore, they are separate	

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		conditions that have distinct treatment pathways in UK clinical practice. Supporting references • Ruff *et al.*, 2018. The association between atopic dermatitis and hand eczema: a systematic review and meta-analysis. British Journal of Dermatology Volume 178, Issue 4, 2018. • Diepgen *et al.*, 2015 Guidelines for diagnosis, prevention and treatment of hand eczema–short version. Journal of the German Society of Dermatology. Volume 13, Issue 1, 2015. • English *et al.*, 2009. Consensus statement on the management of chronic hand eczema. Clinical & Experimental Journal. Volume 34, Issue 7, 2009. • The trial data currently available for abrocitinib is for trials including patients with atopic dermatitis not chronic hand eczema. Therefore, it would not be feasible to compare abrocitinib with alitretinoin in chronic hand eczema based on the currently available trial evidence. In addition, in relation to baricitinib being defined in the draft scope, we would like to seek clarification from NICE around when treatments that are currently within the NICE process will be deemed a relevant comparator for a treatment going through scoping. There is inconsistency around the timepoints for drugs going through the NICE process being considered as a comparator and this needs to be more clearly defined so that manufacturers can suitably prepare evidence for NICE appraisals.	

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		For this appraisal, at the time of receiving the NICE draft scope for abrocitinib, the first appraisal meeting for baricitinib had not been conducted and it will be several months before an ACD/FAD will be published. Further there is no guarantee that baricitinib will receive a positive recommendation. Including comparators at such an early timepoint creates substantial challenges for companies given that clinical data published tends to be more limited and also, in any NICE materials published, trial data is confidential.	
	National Eczema Society	Yes, these are the standard treatments for moderate to severe atopic eczema currently used in the NHS with which the technology should be compared. We are unable to describe any one of these as 'best alternative care' – which would be 'best alternative care' would depend on the individual. It should be noted that most current immunosuppressive drug treatments are not licenced for children, but are prescribed off-licence in the absence of alternatives.	Thank you for your comment. No action required.
	Eczema Outreach Support	No comments	Thank you. No action required.
Outcomes	Pfizer	The outcomes within the draft scope capture the most important health-related benefits of abrocitinib.	Thank you for your comment. No action required.
	National Eczema Society	Yes, these outcome measures will capture the most important health-related benefits (and harms) of abrocitinib.	Thank you for your comment. No action required.
	Eczema Outreach Support	Add psycho-social impact, as mentioned above and below.	Thank you for your comment. It is considered that psycho-

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			social impact is included under health-related quality of life, so it is not necessary to specify separately. No action required.
Economic analysis	Pfizer	No comment	Thank you. No action required.
	National Eczema Society	N/A	Thank you. No action required.
	Eczema Outreach Support	"*Costs will be considered from an NHS and Personal Social Services perspective.*" Also include personal costs (eczema related expenditure such as hospital trips, special clothing, diets, employment loss…)	Thank you for your comment. The NICE methods guide stipulates costs should relate to resources that are incurred by the NHS and personal and social services in the reference case analysis. Costs borne by patients may be included when they are reimbursed by the NHS or personal social services. Where there are costs borne by patients that are not reimbursed by the NHS

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			and personal social services, these may be presented separately. Productivity costs should not be included. No changes made to the scope.
Equality and Diversity	Pfizer	No concerns identified	Thank you for your comment. No action required.
	National Eczema Society	We do not think the proposed remit and scope require changing [in order to promote equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others].	Thank you for your comment. No action required.
	Eczema Outreach Support	There should be special consideration given to 2 groups because of their higher needs for education and support: - Adolescents - “hard to reach” communities (BAME, low socio-economic backgrounds, etc.) Both may experience health inequalities in regards to access/adherence to eczema treatments.	Thank you for your comment. NICE does not routinely use age to define subgroup analyses. In previous atopic dermatitis scopes, the appraisal has either looked at adults only, people aged 12-17 only, or all people aged 12 or over, based on the anticipated marketing authorisation and

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			clinical trial evidence. Additionally, the scope includes subgroup analyses by skin colour, which could be considered to include BAME individuals; however, subgroups should be clinically meaningful and definable, therefore, 'low socio-economic background' is unlikely to meet these criteria. The appraisal committee will assess the technology using the data presented to it in the company submission documents. The committee will consider whether its recommendations could have a different impact on people protected by the equality legislation than on the wider population. No change has been made to the scope.

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Other considerations	Pfizer	Prespecified subgroup analysis will be presented in the submission materials for abrocitinib although we would like to highlight some considerations relating to subgroups that are relevant to the appraisal and also inconsistency with other ongoing appraisals: • **People with moderate dermatitis and those with severe dermatitis:** There is inconsistency in the incorporation of moderate and severe disease as a subgroup across ongoing appraisals; this subgroup is not listed as relevant within the published draft scope for tralokinumab [ID3734] and upadacitinib [ID3733] • **People with atopic dermatitis affecting the hands:** The clinical trial programme for abrocitinib was not designed to measure the effect on localised areas of the body such as hand eczema. Although it is likely that abrocitinib would have an effect on hand eczema there were no outcomes for hand eczema in available clinical trial data against which this can be measured. • **People who require rescue treatment due to flares:** Rescue medications were not allowed within pivotal studies (JADE MONO-1/2, JADE TEEN and JADE COMPARE) for abrocitinib and therefore it will not be possible to consider subgroup data for 'people who require rescue treatment due to flares,' except potentially considering JADE REGIMEN which is ongoing. A subgroup of people for whom therapies have been inadequately effective, not tolerated or contraindicated should also be included. This is also listed as relevant within the published draft scope for tralokinumab [ID3734] and upadacitinib [ID3733].	Thank you for your comment. The subgroup of people for whom systemic therapies have been inadequately effective, not tolerated or contraindicated has been included in the scope. The subgroup of people who require rescue treatment due to flares has been removed from the scope. The subgroups based on severity have been retained for consistency with TA681, in which the ERG considered that it would have been beneficial to present separate subgroups of moderate and severe AD.

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	National Eczema Society	N/A	Thank you. No action required.
	Eczema Outreach Support	No comments	Thank you. No action required.
Innovation	Pfizer	We consider abrocitinib to be innovative in its potential to make a significant and substantial impact on health-related benefits and improve the way that current need is met. Abrocitinib has a novel mechanism of action in that it is an orally administered, JAK1-selective inhibitor that inhibits several key cytokine signalling pathways known to have an important role in the pathophysiologic characteristics of atopic dermatitis, , including thymic stromal lymphopoietin (TSLP), IL-4, IL-13, IL-22 and IL-31. The results of pivotal studies for abrocitinib demonstrate efficacy of the treatment for patients with moderate-to-severe atopic dermatitis across a broad range of clinically and patient relevant endpoints, as will be further demonstrated in the submission documentation for this appraisal. The availability of abrocitinib is important in providing both patients and clinicians with an additional treatment option for moderate to severe atopic dermatitis in the context of limited treatment options.	Thank you for your comment. The appraisal committee will consider the extent to which abrocitinib is innovative in its decision making. No action required.
	National Eczema Society	Yes, we consider the technology to be innovative, in that it has a JAK inhibitor mode of action. Abrocitinib is one of several JAK inhibitor technologies currently being assessed by NICE. It has the potential to make	Thank you for your comment. The appraisal committee will consider

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		a significant and substantial impact on health-related benefits and improve the way that current need is met. It is also beneficial that abrocitinib is being considered for use to treat adolescents aged 12-17 years, as well as adults, and that this treatment if approved will be available for them at the same time as for adults. Often children have to wait several years for access to treatment after approval for use in adults. The introduction of JAK inhibitors like abrocitinib would not necessarily lead to a 'step-change' in the management of eczema. Nevertheless, its availability would broaden the range of treatments available for patients, which is vital given the limited treatment options for the condition at present and increase the likelihood that people with moderate to severe eczema would have access to a treatment that is effective for them. This is very important and necessary given the heterogeneous nature of eczema. People with moderate to severe eczema are currently faced with the choice of managing the best they can with topical treatments, in great pain and discomfort, or starting phototherapy (which is not universally available) or immunosuppressant drugs of uncertain efficacy with the potential for significant long-term harm through severe adverse side effects. The biologic drug dupilumab has fewer potential side effects than immunosuppressant drugs, but it is only available to people who have tried and failed on at least one oral immunosuppressant drug, and those who would not be eligible to take them. In addition, dupilumab does not work effectively for everyone. JAK inhibitors such as abrocitinib work in a different way to biologics. Their mechanism of action, which involves inhibiting a wide spectrum of cytokines that may cover existing and potential inflammatory pathways, is likely to work more effectively for some people than biologics.	the extent to which abrocitinib is innovative in its decision making. No action required.

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		Abrocitinib has the advantage of being taken in pill form, in a single daily dose. Many people with eczema, especially children, prefer oral over injectable drugs. Phase 3 trial data for abrocitinib show that both doses (100mg and 200mg) are generally well-tolerated in adolescents and adults with moderate to severe atopic eczema, and improve signs and symptoms of eczema based on Investigator Global Assessment (IGA) response and Eczema Area and Severity Index (EASI) improvement. The top-line results of the phase 3 JADE COMPARE trial, which evaluated the safety and efficacy of both doses of abrocitinib and background topical therapy against dupilumab and placebo, show a statistically superior reduction in itch by week 2 for patients on abrocitinib 200mg compared with dupilumab. The 200mg dose appears to be the more effective, but is associated with a higher frequency of adverse events. Adverse events occurred among a significant minority of patients in the abrocitinib 200mg treatment arms in some of the trials. The most common adverse events included nausea and headache. In the JADE MONO-2 phase 3 trial, thrombocytopenia was reported in 3.2% of the 200mg group. Even if abrocitinib is only made available under the same circumstances as dupilumab (or as a treatment for people for whom dupilumab is not appropriate or has not proven effective), it will constitute an additional treatment option for people with moderate to severe eczema, increasing the likelihood that they will find a treatment that works effectively for them. In	

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		addition, it has the potential to reduce the need for topical steroid treatment, which people with severe eczema desperately want and deserve.	
	Eczema Outreach Support	Yes I do consider this treatment option to be innovative. Other benefits refer to the psycho-social impact of eczema mentioned above.	Thank you for your comment. The appraisal committee will consider the extent to which abrocitinib is innovative in its decision making. No action required.
Questions for consultation	Pfizer	No further comments	Thank you. No action required.
	National Eczema Society	N/A	Thank you. No action required.
	Eczema Outreach Support	*Comparators* • *How should best supportive care be defined?* Agree with scope's description however <u>patient education and emotional support</u> are missing. They are both crucial to achieving best supportive care.	Thank you for your comment. It is considered that emotional support is included under psychological support, so it is not necessary to specify separately. Education has been included in the definition of best supportive care.
	Pfizer	We would also like to address the reference to a Multiple Technology Appraisal (MTA). We do not currently think that this is necessary or	Thank you for your comment. It is

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Additional comments on the draft scope		appropriate given the ongoing appraisal process. We would encourage NICE to engage directly with Pfizer if this is something that is being explored in the future.	anticipated that this will be a single technology appraisal. No action required.
	National Eczema Society	N/A	Thank you. No action required.
	Eczema Outreach Support	No comments	Thank you. No action required.

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

Neonatal and Paediatric Pharmacists Group (NPPG)

Sanofi