

National Institute for Health and Care Excellence

Health Technology Evaluation

Ruxolitinib cream for treating moderate atopic dermatitis after topical corticosteroids and calcineurin inhibitors (ID6602)

Response to stakeholder organisation comments on the draft remit and draft scope

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 and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Incyte Biosciences UK Limited (Company)	Incyte agrees that the proposed evaluation of ruxolitinib and the evaluation route (single technology appraisal) are appropriate.	Thank you for your comment. No action required
	LEO Pharma (comparator)	LEO Pharma (comparator) confirm agreement that this is a suitable topic for a Single Technology Appraisal process.	Thank you for your comment. No action required
	Pfizer Ltd (comparator)	We agree with the appropriateness of the evaluation and proposed evaluation route (single technology appraisal).	Thank you for your comment. No action required
	British Association of Dermatologists (professional)	We agree with the appropriateness of the evaluation of this topic via an STA. We recommend an amendment to the STA title, i.e. "Ruxolitinib cream 1.5% for treating moderate atopic dermatitis".	Thank you for your comment. The title and remit have been updated.

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	Eczema Outreach Support (patient group)	We believe the proposed route is very appropriate for this treatment as it is an innovative therapy focused specifically on treating moderate eczema with limited direct comparators. This focused Single Technology Appraisal may speed up the evaluation process meaning a quicker decision and that patients will ultimately be able to access the treatment faster, if it is successful.	Thank you for your comment. No action required
	Eczema UK (Formerly National Eczema Society; patient group)	<p>Eczema UK agrees that it is appropriate for NICE to evaluate ruxolitinib for treating moderate atopic dermatitis, given the significant physical, psychological and quality-of-life burden associated with eczema, including for people whose disease may be categorised as “moderate” but nevertheless remains highly impactful.</p> <p>Eczema UK considers the proposed Single Technology Appraisal route to be appropriate, as ruxolitinib is a single intervention being considered within a defined indication. However, the evaluation should carefully consider where ruxolitinib would sit within the existing treatment pathway, particularly as an alternative/additional treatment for eczema patients who are not achieving adequate control using emollients, topical corticosteroids or topical calcineurin inhibitors, and who may not be candidates for systemic or advanced therapies.</p> <p>Eczema UK would encourage NICE to ensure that the appraisal fully reflects patient-important considerations, including itch, sleep disturbance, flare frequency, treatment burden, quality of life, and the impact of eczema on work, education and daily functioning. The evaluation should also give careful attention to equality considerations, particularly assessment and treatment outcomes in people with skin of colour.</p> <p>On balance, Eczema UK supports the proposed STA route, provided the scope allows adequate consideration of the treatment pathway, relevant comparators, patient-reported outcomes and health inequalities.</p>	Thank you for your comment. These considerations will be taken into account during the technology appraisal. No action required.

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Wording	Incyte Biosciences UK Limited (Company) (Company)	Incyte recommends revising the remit to align with the anticipated marketing authorisation for ruxolitinib cream: "To appraise the clinical and cost effectiveness of ruxolitinib within its anticipated marketing authorisation for treating adults with moderate atopic dermatitis for whom topical corticosteroids and topical calcineurin inhibitors are inadequate or inappropriate.	Thank you for your comment. The title and remit were kept broad to align with the range of clinical trials as the marketing authorisation was confidential. This has now been updated to align with the company preferred wording.
	LEO Pharma (comparator)	LEO Pharma (comparator) confirm that the wording of the remit reflects the issues of clinical and cost effectiveness most pertinent to this technology.	Thank you for your comment. No action required
	Pfizer Ltd (comparator)	Yes	Thank you for your comment. No action required
	British Association of Dermatologists (professional)	We recommend small changes to the remit, "To appraise the clinical and cost effectiveness of ruxolitinib cream 1.5% within its likely marketing authorisation for treating moderate atopic dermatitis."	Thank you for your comment. The remit has been updated.
	Eczema Outreach Support (patient group)	The remit broadly captures the key issues of clinical and cost effectiveness, however, the wording could be strengthened to better reflect how the treatment is expected to be used in practice.	Thank you for your comment. The remit has been updated.

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		<p>In particular, the remit should explicitly clarify the intended place of the treatment within the care pathway, including whether use in primary care settings is anticipated alongside specialist care.</p> <p>The wording should also clearly define the eligible age range, as many treatments for atopic dermatitis have minimum age restrictions and this will be important so that the appraisal reflects the population that the treatment would be licensed for.</p> <p>Clarifying these aspects could help ensure a more complete evaluation.</p>	
	Eczema UK (Formerly National Eczema Society; patient group)	<p>The wording of the remit broadly reflects the key issues of clinical and cost effectiveness that NICE should consider for ruxolitinib in moderate atopic dermatitis. Eczema UK believes it is important the evaluation fully captures the substantial burden experienced by people with moderate disease, including quality-of-life impacts, chronic itch, sleep disturbance, visible skin changes and psychosocial burden, which may not always be reflected fully using established disease severity measures alone.</p> <p>Eczema UK also encourages NICE to ensure that the evaluation considers the potential role of ruxolitinib within the wider treatment pathway, particularly for people whose condition is inadequately controlled with existing topical therapies but who may not yet be eligible for, suitable for, or willing to use systemic treatments that carry higher risks of adverse effects.</p> <p>Eczema UK supports the inclusion of subgroup considerations relating to hand eczema involvement and skin colour, as these are clinically and socially</p>	<p>Thank you for your comment.</p> <p>The impacts on the quality of life and severity measures used to capture this will be discussed in more detail during the appraisal and by the committee with input from the company submission, clinical experts and patient groups.</p>

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		<p>important considerations that may affect disease recognition, severity assessment and treatment outcomes.</p> <p>No alternative wording is proposed, although Eczema UK would welcome explicit recognition within the scope of patient-reported outcomes and treatment burden as important components of clinical effectiveness.</p>	
Additional comments on the draft remit	Incyte Biosciences UK Limited (Company)	<p>Timing issues: Patients with moderate atopic dermatitis (mAD) for whom topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) are inadequate or inappropriate continue to face important therapeutic limitations. Even when classified as “moderate,” patients may experience substantial symptom burden, quality of life (QoL) impairment and a need for effective, durable, and well-tolerated treatment options before escalation to advanced systemic therapies.</p> <p>For these patients, the next treatment step currently involves escalation to conventional systemic immunosuppressive therapy, many of which are used off label. Although these therapies may be appropriate for selected patients, they are associated with important practical and clinical limitations, including the need for baseline and ongoing laboratory monitoring, contraindications and drug-drug interaction considerations, tolerability issues, and safety concerns related to systemic immunosuppression and potential cumulative toxicity. These requirements can impose a substantial burden on patients, carers, and healthcare professionals, particularly for patients with moderate disease whose symptoms remain inadequately controlled with topical therapy, but who may not require, or may not be suitable for, advanced systemic treatment.</p> <p>Advanced systemic therapies, including biologics and Janus kinase inhibitors (JAKis), have expanded treatment options for appropriate patients. However, due to NICE reimbursement restrictions, they are generally reserved in UK clinical practice for patients who have failed at least 1 conventional systemic</p>	Thank you for your comment. No action required

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		<p>immunosuppressive treatment, or for whom such treatment is unsuitable (8-14). Accordingly, they remain specialist treatment options rather than routine alternatives for the wider mAD population. This highlights the need for effective, well-tolerated topical options for mAD that can address persistent disease activity as an alternative to systemic immunosuppressive therapy.</p> <p>Ruxolitinib 1.5% cream is a topical JAKi indicated for the treatment of adult patients with mAD for whom TCSs and TCIs are inadequate or inappropriate and has demonstrated efficacy in a phase 3 clinical trial, TRuE-AD4. Therefore, ruxolitinib may provide a treatment option that combines effective symptom control, acceptable tolerability, and a practical mode of administration which could address an important gap in care.</p>	
	LEO Pharma (comparator)	Timing issues: LEO Pharma (comparator) have no comments on the timing of the NICE appraisal.	Thank you for your comment. No action required
	Pfizer Ltd (comparator)	Timing issues: Ruxolitinib (Opzelura) does not currently have a marketing authorisation in the UK for moderate atopic dermatitis (AD). It has been studied in placebo-controlled clinical trials in people with atopic dermatitis but the current information makes it difficult to define the specific population. As a result it is also difficult to determine specific sub groups based on age and severity of disease. This information is critical in understanding the appropriate comparator.	Thank you for your comment. The population and remit have been updated to better reflect the anticipated marketing authorisation. Further information on the population and relevant comparators can be provided by the company at the submission stage of the appraisal.

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	British Association of Dermatologists (professional)	We recommend small changes to the remit, "To appraise the clinical and cost effectiveness of ruxolitinib cream 1.5% within its likely marketing authorisation for treating moderate atopic dermatitis."	Thank you for your comment. The remit has been updated.
	Eczema Outreach Support (patient group)	<p>Timing issue: There is a high level of urgency for this evaluation within the NHS. Data from our service indicates that many patients report waiting times of 1–3 years to access secondary care, with some reporting waits of up to 5 years. During this period, treatment options in primary care are limited, leaving many patients without adequate control of the condition.</p> <p>This is being compounded by increasing wide-spread concern about topical steroid use. Increasing worries about Topical Steroid Withdrawal are reflected in patient feedback to our charity via one to one support calls, peer support services and through our online community. As a result, some patients are reluctant to use steroids, meaning they may go without effective treatment while waiting for specialist care. This creates a clear gap in treatment options within primary care.</p> <p>Our annual survey further highlights this unmet need, with 76% of families reporting that one of their biggest concerns in managing eczema is that treatments are not working (EOS, March 2026).</p> <p>There is therefore an urgent need for additional effective and acceptable treatments that can be prescribed earlier in the care pathway. Providing an alternative treatment option in primary care could help bridge the gap between initial management and access to specialist services, reducing avoidable deterioration in patients' condition and the wider impacts on carers and families.</p> <p>Overall, timely evaluation of this treatment could help address current unmet need, improve patient outcomes, and reduce pressure on secondary care services.</p>	Thank you for your comment. No action required

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	Eczema UK (Formerly National Eczema Society; patient group)	<p>Timing issue: Eczema UK considers this evaluation to be of moderate-to-high urgency for the NHS. There remains substantial unmet need for people living with moderate atopic dermatitis whose condition is not adequately controlled with currently available topical therapies, but who may not yet meet thresholds for systemic or advanced therapies.</p> <p>Atopic dermatitis can and does have a major impact on quality of life, including persistent itch, sleep disturbance, pain, psychological distress, social isolation, impacts on work or education, and repeated healthcare utilisation. Delays in accessing effective treatment can contribute to worsening disease burden and reduced wellbeing for patients and their families.</p> <p>Eczema UK also notes that the treatment landscape for atopic dermatitis is evolving rapidly, with increasing availability of targeted therapies. Timely evaluation of ruxolitinib is therefore important to ensure equitable and evidence-based access where clinically appropriate, and to provide clarity for clinicians and patients regarding its place within the treatment pathway.</p>	Thank you for your comment. No action required

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Incyte Biosciences UK Limited (Company)	Incyte notes that the background section states “atopic dermatitis can affect any part of the body but it most often affects the hands in adults”. However, the cited reference only notes that AD “can appear in different areas of the body, but it’s common on the elbows, knees and hands”, which does not substantiate the claim that the hands are the most frequently affected site in adults (17). Technology appraisal guidance published by NICE on topical corticosteroids for AD states that the disease “affects mainly the flexor	Thank you for your comment. The background section has been updated.

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		<p>surfaces of the elbows and knees, as well as the face and neck” (18). Therefore, Incyte would like to highlight that the statement regarding the hands being the most frequently affected part of the body is not reflected in published literature.</p> <p>Incyte would also like to highlight a possible inaccuracy in the proportion of patients with moderate to severe disease who require systemic treatment. The background information section states that 62% of patients with moderate to severe disease require systemic treatment, however, the cited reference states that “36.7% of patients with moderate to severe AD were prescribed systemic agents” (20).</p>	
	LEO Pharma (comparator)	LEO Pharma (comparator) have no comments on the background information.	No action required
	Pfizer Ltd (comparator)	The background information is accurate however consider referencing prior scopes for consistency alongside NIHRIO briefing documents (see additional comments below).	Thank you for your comment. Additional comments have been addressed in respective sections below.
	British Association of Dermatologists (professional)	<p>We recommend the following edits (underlines/strikethroughs in green):</p> <p>“Atopic dermatitis (also known as atopic eczema) is a long-term condition that affects the skin. It is characterised by a blotchy rash, dry, itchy and inflamed skin, <u>often associated with background dryness.</u>”</p> <p>“Of the people with atopic dermatitis, 8% will have moderate-to-severe disease. Around 62% of these people will <u>may</u> need systemic treatment.”</p> <p><u>“Mild atopic dermatitis is usually managed in primary care; moderate-to-severe cases are also managed in primary care but referred to secondary care for uncontrolled disease.”</u></p>	<p>Thank you for your comment. The background section is intended as a general summary. We have made some updates for clarity.</p> <p>As this topic is for adults with atopic dermatitis, we have not</p>

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		<p>“Second-line treatment options include topical calcineurin inhibitors (technology appraisal guidance 82). <u>Referral to secondary care is recommended for patients whose eczema is not controlled, or for other concerns (NICE clinical guideline CG57 for atopic eczema in under-12s, section 1.7.1.3).</u>”</p> <p>“People with moderate or severe atopic dermatitis not responding to topical treatments may be referred to secondary care and offered stronger oral medications such as oral steroids or <u>conventional systemic immunomodulatory drugs</u> immunosuppressants (methotrexate and azathioprine, sometimes ciclosporin, mycophenolate mofetil).” N.B. The original list is out of date – oral steroids, azathioprine and MMF are hardly used for atopic dermatitis (AD) these days.</p> <p>Additionally, the list of biologics and JAK inhibitors needs rearranging to...</p> <ol style="list-style-type: none"> 1. <u>dupilumab</u> 2. <u>abrocitinib / upadacitinib / baricitinib</u> 3. <u>nemolizumab / lebrikizumab / tralokinumab</u> <p><u>...based on individual patient factors.</u></p> <p>Finally, the ‘Intervention(s)’ section in the table should read, “Ruxolitinib <u>cream 1.5%</u>”.</p>	<p>updated the background section to include management of patients who are under 12 years old.</p> <p>The treatments listed in have been retained as the scope intends to be broad and cover treatments for the full population. They have been rearranged.</p>
	Eczema Outreach Support (patient group)	<p>Describing Atopic Dermatitis (AD) as a “blotchy rash” diminishes the vast and wide-ranging impact it has on the entire person and reduces the condition to a “skin complaint” which is how it is widely misunderstood in society.</p> <p>AD is associated with a wide range of comorbidities and has significant mental health impacts that are often underrepresented. Patients frequently experience conditions such as asthma and food allergies, alongside increased risk of skin infections. The burden of the disease also extends beyond the physical symptoms, with many people experiencing anxiety, depression, sleep disturbance and social isolation due to persistent itch, visible symptoms and stigma. These impacts can affect education,</p>	<p>Thank you for your comment. The background section has been updated to reflect the mental health impacts of the condition.</p>

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		employment, relationships and overall quality of life, highlighting the need for a more holistic understanding of disease burden within the appraisal.	
	Eczema UK (Formerly National Eczema Society; patient group)	<p>Eczema UK agrees the background information provides a broadly accurate overview of atopic dermatitis, current treatment approaches and the existing NHS treatment pathway. Eczema UK particularly welcomes recognition of the substantial burden associated with chronic itch, inflammation, skin breakdown and infection risk.</p> <p>However, Eczema UK believes the background section could more fully reflect the wider psychosocial and quality-of-life burden associated with atopic dermatitis, including sleep disturbance, mental health impacts, social stigma, educational and occupational impacts, and the burden placed on families and carers. These impacts can be significant even in people classified as having 'moderate' disease.</p> <p>Eczema UK also suggests acknowledging disease severity and visibility may present differently across skin tones, which can contribute to delayed diagnosis, under-recognition of severity and inequalities in care for people with skin of colour.</p> <p>In addition, while the background appropriately outlines systemic and advanced treatment options, it could better recognise the unmet need among people whose disease is inadequately controlled with topical therapies but who may not yet be suitable for systemic immunosuppressants or biologic therapies. This group may experience substantial ongoing disease burden despite being categorised as having moderate disease.</p> <p>Finally, Eczema UK notes that treatment burden itself is an important consideration in atopic dermatitis management, including frequent application of topical treatments, concerns regarding long-term topical corticosteroid use, and adherence challenges associated with complex treatment regimens.</p>	<p>Thank you for your feedback. The background section has been updated to reflect the mental health impacts of the condition.</p> <p>Equality issues relating to skin colour have been included in the equality impact assessment.</p> <p>The background section is intended to be a very brief summary of the condition. Further information about the unmet need can be provided at the submission stage of the appraisal.</p>

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Population	Incyte Biosciences UK Limited (Company)	<p>Incyte recommends revising the population to align with the anticipated marketing authorisation and intended clinical use of ruxolitinib cream, as follows:</p> <p>“Adults with moderate atopic dermatitis for whom topical corticosteroids and topical calcineurin inhibitors are inadequate or inappropriate.”</p> <p>This amendment is important because the current population is broader than the anticipated licensed population and may include patients who remain suitable for, and adequately managed with, topical corticosteroids or topical calcineurin inhibitors. Aligning the scope with the marketing authorisation will ensure that the appraisal focuses on the clinically relevant population and the appropriate place of ruxolitinib cream in the treatment pathway.</p>	Thank you for your comment. The population has been updated to reflect the anticipated marketing authorisation.
	LEO Pharma (comparator)	LEO Pharma (comparator) have no comments on the background information.	Thank you. No action required
	Pfizer Ltd (comparator)	<p>The population as defined is unclear. Comparators included in the draft scope should align with positioning aligned with expected label.</p> <p>For example, given the current positioning of ruxolitinib in vitiligo TA1140 based on its label the committee anticipated that it would be prescribed, supplied and monitored in secondary care. This aligns with the comparators identified in the current scope for AD. Therefore, the population as defined here may be too broad and might be more appropriately defined as “People with moderate atopic dermatitis suitable for conventional or advanced systemic therapy” as this aligns with the comparator section</p>	Thank you for your comment. The population has been updated in line with the anticipated marketing authorisation.
	British Association of Dermatologists (professional)	Ideally, the population should cover people with moderate AD aged 2 years and over, as there have been clinical trials evaluating ruxolitinib cream in children with AD aged 2-11 years (https://pubmed.ncbi.nlm.nih.gov/40378883/ ,	Thank you for your comment. The population has been updated in line with the

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		<p>https://pubmed.ncbi.nlm.nih.gov/39760983/), adolescents aged ≥ 12 years (https://pubmed.ncbi.nlm.nih.gov/38698175/) and adults (https://pubmed.ncbi.nlm.nih.gov/36574595/).</p>	<p>anticipated marketing authorisation.</p>
	<p>Eczema Outreach Support (patient group)</p>	<p>The scope should clearly specify the exact age group for which the treatment is intended, as many Atopic Dermatitis therapies have minimum age requirements and better understanding the target population will result in a more appropriate evaluation.</p> <p>Clarity required on comparators. Will ruxolitinib only be accessible to patients after they have tried another therapy and if yes, which one(s)?</p>	<p>Thank you for your comment. The population has been updated in line with the anticipated marketing authorisation.</p>
	<p>Eczema UK (Formerly National Eczema Society; patient group)</p>	<p>The population is broadly defined as people with moderate atopic dermatitis. However, Eczema UK believes it will be important for the evaluation to recognise that ‘moderate’ atopic dermatitis can still be associated with substantial physical, psychological and social burden, including severe chronic itch, sleep disturbance, visible skin involvement, pain, mental health impacts and reduced quality of life.</p> <p>Eczema UK also notes that severity classifications do not always fully reflect patient experience or disease burden in clinical practice. Some people with so-called moderate disease may experience significant impairment despite not meeting thresholds for systemic or advanced therapies.</p> <p>The organisation welcomes the inclusion of subgroup considerations relating to people with atopic dermatitis affecting the hands and skin colour subgroups. These are important clinical and equality considerations, particularly given the functional impact of hand eczema and known disparities in disease recognition and assessment in people with skin of colour.</p> <p>Eczema UK would encourage NICE to ensure that the population definition and evidence assessment adequately capture diversity in age, ethnicity, skin</p>	<p>Thank you for your comment. The population has been updated in line with the anticipated marketing authorisation.</p> <p>The scope is intended to be a brief summary of the appraisal. Further information about severity classifications and access to treatment can be provided at the submission stage of the appraisal.</p> <p>Equality issues relating to skin colour and ethnicity have been</p>

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		tone and disease presentation, as well as the fluctuating and relapsing nature of eczema over time.	included in the equality impact assessment.
Subgroups	Incyte Biosciences UK Limited (Company)	<p>Incyte does not consider a separate subgroup of people with AD affecting the hands to be appropriate for inclusion in the scope for the following reasons:</p> <ol style="list-style-type: none"> 1. The pivotal trial population does not support a hand-only subgroup analysis, because the protocol excluded “presence of AD lesions only on the hands or feet without prior history of involvement of other classic areas of involvement such as the face or the flexural folds”. 2. There is also an important mismatch in outcome measurement. In the TRuE-AD4 trial supporting the submission, efficacy was assessed using standard AD endpoints, including EASI, IGA-TS, Itch NRS and SCORAD. By contrast, a hand eczema population would usually be assessed using hand-specific endpoints such as IGA-CHE treatment success, HECSI-75, HECSI-90, HECSI score reduction, HESD pain, and HESD itch. 3. Patients with hand involvement as part of broader AD were included within the overall TRuE-AD4 trial population, with approximately two-thirds of patients having hand involvement at baseline (54 patients [66.7%] in the vehicle group and 106 patients [66.3%] in the ruxolitinib group). This supports consideration of hand involvement within the overall AD population. However, the available evidence does not support a distinct evaluation of isolated hand disease. 4. AD affecting the hands represents a distinct phenotype of the disease, whereas this submission focuses on a broader mAD patient population in line with the anticipated marketing authorisation. <p>Skin colour was not a pre-specified subgroup in the TRuE-AD4 trial and was not collected directly. Although race was collected, this is not an adequate proxy for skin colour for the purposes of a robust subgroup analysis. The trial was not designed or powered to evaluate differential treatment effects by skin</p>	Thank you for your comment. Where possible, analysis of subgroups noted in the scope should be provided. The company will have the opportunity to justify any exclusion of these subgroups or inclusion of additional subgroups in their submission.

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		colour. While skin colour may affect disease presentation and assessment, the available evidence does not establish a differential treatment effect by skin colour. The available trial evidence therefore does not support inclusion of a separate skin colour subgroup in this appraisal.	
	LEO Pharma (comparator)	LEO Pharma (comparator) note that one subgroup comprises 'patients with atopic dermatitis involving the hands'; importantly, this is not synonymous with chronic hand eczema, a separate and heterogeneous disorder marked by distinct inflammatory endotypes, encompassing irritant and allergic contact dermatitis and differing immunologically according to the presence or absence of comorbid atopic dermatitis.	Thank you for your comment. The scope has been updated to include the subgroup site of atopic dermatitis.
	Pfizer Ltd (comparator)	<p>We propose that these additional subgroups should also be considered:</p> <ul style="list-style-type: none"> • People with atopic dermatitis affecting the head and neck. • People with atopic dermatitis affecting delicate places (i.e. eyelids, genitals etc). • People with atopic dermatitis based on skin colour <p>Given the route of administration and the current unmet need subgroups could be considered relevant for any body area. For example, head and neck, associated with greatest unmet need along with skin colour where there is a lack of evidence and guidance in this cohort.</p>	Thank you for your comment. The scope has been updated to include the subgroup site of atopic dermatitis.
	British Association of Dermatologists (professional)	<p>We recommend adding:</p> <ul style="list-style-type: none"> • Age (e.g. 2-12; 13-17; ≥18 years) • People with AD affecting the face vs. other sites 	Thank you for your comment. The scope has been updated to include the subgroup site of atopic dermatitis. This appraisal will evaluate ruxolitinib cream for the adult population (those aged

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	Eczema Outreach Support (patient group)	<p>Yes, there are specific groups within the population who may benefit differently from this treatment and should be considered separately:</p> <ul style="list-style-type: none"> - Neurodivergent children and adults may benefit from this being a topical treatment, as topicals can be more tolerable than tablets or injections for them. Topical treatments can also be self administered at home which can be especially impactful for neurodivergent patients as it provides flexibility to apply them at a time and place that works best for them. However, some neurodivergent patients may still experience challenges with topical treatments and this variability should be recognised. - AD can present differently in children and young people and adults and the impacts can vary depending on life-stage. Children/young people can be more affected by sleep disruption and impacts on family life, while adults may experience greater impacts on work and mental health. - In addition, whilst we recognise that skin colour is mentioned as a subgroup in the scope, we must stress that people with different skin tones should be considered; the condition can present differently in darker skin tones leading to late and/or misdiagnosis. Patients with darker skin tones are also often underrepresented in clinical trials. - People who face practical barriers to attending appointments, such as those with limited mobility, caring responsibilities or who live in more remote areas, may benefit more from a treatment that can be managed in their local community or at home. 	<p>18 years old and above).</p> <p>Thank you for your comment. Subgroups should be preferably identified because of known, biologically plausible mechanisms, social characteristics, or other clearly justified factors. This does not prevent the identification of subgroups later in the process.</p> <p>The impact on neurodivergent people, skin colour and limited mobility have been included in the equality impact assessment.</p>
	Eczema UK (Formerly National	Eczema UK supports the inclusion of the proposed subgroups relating to people with atopic dermatitis affecting the hands and skin colour subgroups,	Thank you for your comment. The impact of skin colour has been

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	Eczema Society; patient group)	<p>as these are clinically relevant and may influence disease burden, treatment response, quality of life and access to care.</p> <p>Hand involvement can have a particularly significant impact on daily functioning, employment, social interaction and mental wellbeing, even where overall disease severity may otherwise be classified as moderate. Eczema UK therefore considers this to be an important subgroup for separate consideration.</p> <p>Eczema UK also strongly welcomes the inclusion of skin colour subgroups. Atopic dermatitis can present differently across skin tones, and there are recognised inequalities in diagnosis, severity assessment and treatment experiences among people with skin of colour. The organisation encourages NICE to ensure that evidence relating to treatment effectiveness, symptom assessment and quality-of-life outcomes is adequately captured across diverse skin tones.</p> <p>In addition, Eczema UK suggests consideration of:</p> <ul style="list-style-type: none"> • people with high itch burden or significant sleep disturbance despite “moderate” disease classification; • people with recurrent flares or difficult-to-control disease despite topical treatment; • people for whom treatment burden or concerns regarding long-term topical corticosteroid use significantly affect adherence or quality of life. <p>These factors may not always be fully reflected through conventional severity scoring systems but can substantially affect patient experience and healthcare need.</p>	included in the equality impact assessment.
Comparators	Incyte Biosciences UK	Incyte agrees that the comparators listed are considered standard treatments for AD in the NHS and that all relevant comparators have been included.	Thank you for your comment. The comparators have been

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	Limited (Company)	However, Incyte notes that while azathioprine and mycophenolate mofetil are included in NHS guidance for AD as conventional systemic immunosuppressant treatment options (21), they are no longer routinely used as standard treatments in clinical practice, and clinical expert opinion supports this. As such, Incyte does not consider these appropriate comparators for the decision problem.	retained, as those listed in the scope are intended to be broad and cover the relevant comparators for the full population in the scope. The most appropriate comparator(s) will be discussed in more detail during the appraisal and by the committee, with input from the company submission, clinical experts and patient representatives.
	LEO Pharma (comparator)	<p>LEO Pharma (comparator) agree with the comparators in the scope for the two groups identified. It is important to note that an earlier group also exists: patients who have not failed standard topical therapies. For this group topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) are also relevant.</p> <p>Ruxolitinib cream has been evaluated in patients with moderate atopic dermatitis across multiple trials (TRuE-AD1, TRuE-AD2, TRuE-AD3) without requiring prior failure of standard topical therapies. These studies reflect a moderate disease population managed within topical treatment pathways, where TCSs and TCIs remain the established standard of care and relevant treatment alternatives.</p> <p>TRuE-AD4 was designed to assess ruxolitinib cream in patients with moderate atopic dermatitis who had an inadequate response to TCSs and</p>	Thank you for your comment. The population and remit have been updated to reflect the anticipated marketing authorisation. Subsequently, the comparators have not been updated as they now better reflect the relevant comparators.

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		TCIs. When considered alongside the wider clinical evidence, TRuE-AD4 therefore provides data in a more treatment-experienced subgroup, while TRuE-AD1, TRuE-AD2 and TRuE-AD3 inform the use of ruxolitinib cream in patients with moderate disease where TCSs and TCIs remain relevant comparators.	
	Pfizer Ltd (comparator)	<p>Given it's mode of action (MoA) and route of administration (RoA) advance systemic Biologics and JAKs should be considered as comparators. In addition, there would be some value in clearly referencing treatments based on disease severity as several systemic treatments are also indicated in more severe disease in addition to moderate and some studies for non-systemic include mild patients</p> <p>We believe the language around immunosuppressive therapies should be amended to 'conventional systemic therapies (azathioprine, ciclosporin, mycophenolate mofetil and methotrexate)'. This is because these therapies have a less targeted mode of action when compared with 'advanced systemic therapies' such as biologics/JAK inhibitors that are also used for long-term management of AD.</p>	<p>Thank you for your comment. The comparators in the scope are intended to be broad and cover the relevant comparators for the full population in the scope.</p> <p>The most appropriate comparator(s) will be discussed in more detail during the appraisal and by the committee, with input from the company submission, clinical experts and patient representatives.</p> <p>The wording around different treatments for atopic dermatitis have been updated.</p>
	British Association of	We recommend that the comparators for this STA should be:	Thank you for your comment. The comparators in the

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	Dermatologists (professional)	<ul style="list-style-type: none"> • First-line conventional systemic immunomodulatory therapy (i.e. methotrexate, ciclosporin). • N.B. Azathioprine may no longer be an appropriate comparator as its use in AD has been dwindling due to long-term toxicities and risk of developing skin cancer. <p>It would be inappropriate to include targeted immunomodulatory therapies like biologics and JAK inhibitors as direct comparators, as ruxolitinib cream should be positioned between first-line topical and first-line systemic therapies, i.e. following TCS failure or its adverse effects preclude further use.</p>	<p>scope are intended to be broad and cover the relevant comparators for the full population in the scope.</p> <p>The most appropriate comparator(s) will be discussed in more detail during the appraisal and by the committee, with input from the company submission, clinical experts and patient representatives.</p>
	Eczema Outreach Support (patient group)	Yes but it should be noted that ruxolitinib is an innovative therapy due to it being a topical JAK inhibitor providing an advanced therapy option for moderate AD.	Thank you for your comment. No action required
	Eczema UK (Formerly National Eczema Society; patient group)	<p>The comparators listed broadly reflect the current treatments used within the NHS for people with moderate to severe atopic dermatitis, particularly within secondary care and for people whose condition has not responded adequately to topical therapies.</p> <p>Eczema UK agrees that systemic immunosuppressants, biologic and JAK inhibitors treatments are relevant comparators within the current treatment pathway. The organisation also recognises the importance of including both established systemic therapies and newer targeted treatments currently used in NHS practice.</p>	Thank you for your comment. The population and remit of the evaluation has been updated to reflect the anticipated marketing authorisation. Subsequently the comparators now better reflect the relevant comparators for this

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		<p>However, Eczema UK notes that the proposed positioning of ruxolitinib may differ from some of the listed comparators because it is a topical treatment rather than a systemic therapy. It may therefore be important for NICE to consider where ruxolitinib is likely to sit in real-world clinical practice, particularly for people whose disease is inadequately controlled with topical corticosteroids or topical calcineurin inhibitors but who may not yet be eligible for, suitable for, or willing to use systemic or advanced therapies.</p> <p>Eczema UK therefore suggests that continued standard topical care, including emollients, topical corticosteroids and topical calcineurin inhibitors, should also be recognised as relevant background or contextual comparators within the treatment pathway, particularly if ruxolitinib is anticipated to be used before escalation to systemic therapy.</p> <p>The organisation also encourages NICE to consider variation in access to advanced therapies across NHS services and the extent to which some systemic treatments may be used differently in routine practice compared with formal guideline pathways.</p>	<p>appraisal. So, any additional comparators have not been included. No action required.</p>
Outcomes	Incyte Biosciences UK Limited (Company)	<p>Incyte considers most of the outcomes listed to be appropriate for AD. However, Incyte would like to highlight the issues that have been raised in previous technology appraisals in AD (TA814 [abrocitinib, tralokinumab, and upadacitinib] (22) and TA1077 [nemolizumab]) (23) regarding the following endpoints:</p> <ul style="list-style-type: none"> • Disease free period/maintenance of remission • Time to relapse/prevention of relapse <p>In response to the final scope in TA814, clinical experts informed the External Assessment Group (EAG) that 'disease free period', 'maintenance of remission', 'time to relapse' and 'prevention of relapse' are not terms that are commonly used in AD clinical practice and are not defined for AD (22).</p> <p>In the phase 3 clinical trial for ruxolitinib in mAD (TRuE-AD4) which supports the submission, no formal time-to-relapse or disease-free endpoints were</p>	<p>Thank you for your comment. The outcomes have been retained as the scope is intended to be broad. The company will have the opportunity to present and justify the use of alternative outcome measures. This will be discussed in more detail during the appraisal by the committee with input</p>

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		conducted. Relapse was assessed as a post-discontinuation outcome, while maintenance is reflected descriptively through sustained response (e.g., EASI50), low rates of loss of response/escape, and proportion of time off treatment due to lesion clearance.	from clinical experts and patient groups. No action required.
	LEO Pharma (comparator)	LEO Pharma (comparator) have no comments on the outcomes listed.	Thank you. No action required
	Pfizer Ltd (comparator)	Yes	Thank you for your comment. No action required
	British Association of Dermatologists (professional)	We agree with the outcomes featured in the table.	Thank you for your comment. No action required
	Eczema Outreach Support (patient group)	<p>Outcome measures should take into consideration the often-significant negative impacts of eczema on mental health and therefore the potential positive mental health impacts of ruxolitinib.</p> <p>Using the QALY framework can mean that the long-term burden of Atopic Dermatitis (AD) is not always captured well and will therefore not capture all the health-related benefits of ruxolitinib. AD is a lifelong condition for many people and its impact can fluctuate and often accumulate over years (especially the mental health/psychological impacts). The framework may not fully capture the day-to-day impact of AD on quality of life. For example, the impacts of:</p> <ul style="list-style-type: none"> • Severe and persistent itch • Sleep disturbance 	Thank you for your comment. The company will have the opportunity to present and justify the use of alternative measures to capture quality of life, as stated in section 4.3.10 of the NICE manual. This will be discussed in more detail during the appraisal and by the committee with input from clinical experts

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		<ul style="list-style-type: none"> • Psychological distress (including anxiety, low mood and social stigma) • Impact on ability to work, study and take part in day-to-day activities • Burden on the whole family and carers, particularly the carers of children. <p>Consideration of additional data sources would help ensure that the full benefits of ruxolitinib are recognised in the appraisal. These may include:</p> <ul style="list-style-type: none"> • Eczema-specific quality-of-life measures e.g. POEM • Qualitative evidence from patient testimonials and surveys • Carer-reported outcomes and family impact data 	and patient groups. No action required.
	Eczema UK (Formerly National Eczema Society; patient group)	<p>The outcomes listed are broadly appropriate and capture many of the key clinical aspects of atopic dermatitis, including disease severity, symptom control, relapse prevention, adverse effects and health-related quality of life.</p> <p>However, Eczema UK believes it is particularly important that the evaluation gives sufficient weight to patient-reported outcomes and the lived experience of eczema. In addition to overall disease severity measures, the appraisal should fully capture outcomes relating to itch, sleep disturbance, pain, treatment burden, mental health and the impact of eczema on daily functioning, employment, education and social participation.</p> <p>Eczema UK strongly supports the inclusion of measures relating to itch improvement, as itch is often one of the most burdensome symptoms experienced by people living with eczema and can significantly affect sleep, concentration and psychological wellbeing.</p> <p>The organisation also encourages NICE to consider:</p> <ul style="list-style-type: none"> • frequency and severity of flares; 	Thank you for your comment. The company will have the opportunity to present and justify the use of alternative measures to capture quality of life, as stated in section 4.3.10 of the NICE manual. This will be discussed in more detail during the appraisal and by the committee with input from clinical experts and patient groups. No action required.

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		<ul style="list-style-type: none"> • speed of symptom improvement; • impact on visible skin symptoms across different skin tones; • reduction in treatment burden and complexity; • patient satisfaction and treatment adherence; • longer-term disease control and maintenance of remission. <p>Eczema UK notes that established clinical severity scoring systems do not always fully reflect the real-world burden of moderate atopic dermatitis or the outcomes most important to patients and families. It will therefore be important that patient-reported quality-of-life and symptom measures are given appropriate consideration alongside clinician-assessed disease measures.</p>	
Equality	Incyte Biosciences UK Limited (Company)	<p>Incyte considers that the appraisal should recognise the potential impact of skin colour and other patient characteristics on the assessment of AD severity and quality of life. EASI may underestimate disease severity in people with darker skin tones, and this should be considered when interpreting clinical severity and response. DLQI may also not fully capture the psychological impact of AD, including anxiety and depression, and responses may be affected by physical, sensory or learning disabilities, or communication difficulties.</p> <p>No equality issues are foreseen if ruxolitinib cream is recommended for use in all patients at the anticipated positioning.</p>	Thank you for your comment. These equality issues will be noted and considered by the committee.
	LEO Pharma (comparator)	<p>Diagnosis and assessment of disease severity can be more challenging in people with brown and black skin, as key clinical signs such as skin reddening (erythema) are more difficult to assess visually. As a result, some individuals with atopic dermatitis in these populations may be misdiagnosed or not diagnosed at all, which could lead to undertreatment. Skin colour</p>	Thank you for your comment. These equality issues will be noted and considered by the committee.

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		<p>subgroups have therefore been identified as one of the two key subgroups of interest in the scope. However, there is a risk that this could exacerbate health inequalities if the availability or quality of evidence differs across skin colour subgroups, potentially leading to more robust conclusions for some groups than others.</p>	
	Pfizer Ltd (comparator)	<p>AD disease severity and prevalence is increased for people with darker skin tones based on their ethnicity¹. British dermatology guidance explicitly recognise that AD appears differently in darker skin tones and that post-inflammatory hyperpigmentation is more common and persistent in UK patients with darker skin tones and is frequently reported as more distressing than AD itself².</p> <p>Though these issues do not exclude specific groups of people from patient access, the impact of the recommendation outcome may differ between different ethnicity groups. We recognise that while a qualitative analysis these equality issues are possible, robust and available data to conduct a quantitative analysis on this issue (i.e. DCEA) may be limited.</p>	Thank you for your comment. These equality issues will be noted and considered by the committee.
	British Association of Dermatologists (professional)	<p>Age of people with AD is an important factor as AD is very common in the paediatric population.</p> <p>Consideration of patient choice, i.e. those who might not want to use TCS therapy.</p> <p>People with AD who do not qualify for systemic immunomodulatory therapy (e.g. due to disease severity, presence of comorbidities or contraindications to these treatments).</p> <p>Please note, the erythema component in assessing disease severity (e.g. EASI) may be underestimated in darker skin tones. Thus, such measures may not be representative in such skin tones.</p>	Thank you for your comment. These equality issues will be noted and considered by the committee.

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		<p>Additionally, inflammatory skin disorders such as AD may have an increased impact on some people with darker skin tones , particularly if AD is affecting sites not often or not easily concealed such as the face and hands as inflammation can lead to pigmentary changes of the skin which can be persistent and potentially stigmatising. Quality of life measures such as the DLQI may not adequately capture impact in older people (question about work, studying, sport) or those who are not in a relationship (question about sexual activity). It is also known to capture anxiety and depression poorly across all groups (two parameters that are commonly negatively influenced by AD).</p>	
	<p>Eczema Outreach Support (patient group)</p>	<p>The remit and scope are appropriate, however, some equality considerations should be taken into account. Certain groups, such as people with darker skin tones, may be underrepresented in the evidence base, which could limit full consideration of their needs.</p> <p>Access may also differ in practice depending on where the treatment is delivered. If available in primary care, it could improve accessibility for patients who face barriers to secondary care, including long waiting times or challenges engaging with specialist services. This is particularly relevant for underserved or more deprived populations, who may be less likely to progress through traditional referral pathways. Earlier access in primary care could help reduce inequalities in access to advanced therapies.</p> <p>It may be helpful for the committee to consider data broken down by socioeconomic status and ethnicity, evidence on access to services and referral pathways, real world use of the treatment and adherence data and patient reported outcomes from diverse populations to ensure potential inequalities are fully considered.</p>	<p>Thank you for your comment. Equality and health inequality issues will be noted and considered by the committee</p>
	<p>Eczema UK (Formerly</p>	<p>Eczema UK welcomes the inclusion of skin colour subgroups within the draft scope and believes this is an important equality consideration. Atopic</p>	<p>Thank you for your comment. These</p>

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	National Eczema Society; patient group)	<p>dermatitis can present differently across skin tones, and there are recognised disparities in diagnosis, severity assessment, treatment experiences and access to specialist care for people with skin of colour. The organisation encourages NICE to ensure that evidence relating to clinical outcomes, symptom presentation and quality-of-life impacts is adequately assessed across diverse skin tones.</p> <p>Eczema UK is concerned that conventional disease severity assessment tools and visual scoring systems may not always accurately reflect disease severity in people with darker skin tones, which could potentially lead to under-recognition of disease burden or unequal access to advanced treatments. NICE should therefore consider evidence on how eczema presents and is assessed across different ethnicities and skin tones.</p> <p>The organisation also notes that the burden of eczema may disproportionately affect some protected groups, including:</p> <ul style="list-style-type: none"> • children and young people, particularly in relation to sleep, education and psychosocial wellbeing; • people with disabilities or mental health conditions, for whom treatment burden and chronic itch may have an additional impact on functioning and wellbeing; • people from socioeconomically disadvantaged backgrounds who may face barriers to accessing specialist dermatology care; • people whose occupations are affected by visible eczema or hand involvement. <p>Eczema UK also encourages NICE to consider whether treatment access requirements, referral pathways or monitoring arrangements could unintentionally disadvantage some groups, particularly where access to dermatology services varies geographically.</p>	equality issues will be noted and considered by the committee.

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		<p>Evidence that would help the committee identify and consider equality impacts includes:</p> <ul style="list-style-type: none"> • data on treatment outcomes across different skin tones and ethnic groups; • patient-reported outcome measures relating to itch, sleep, quality of life and psychosocial burden; • evidence on variation in access to specialist care and advanced treatments; • evidence relating to hand eczema and occupational impact; • qualitative evidence from patients and carers describing lived experience and barriers to care. 	
Other considerations	Incyte Biosciences UK Limited (Company)	No further considerations	Thank you for your comment. No action required
	LEO Pharma (comparator)	N/a	No action required
	Pfizer Ltd (comparator)	<p>Rationale may be needed as to why delgocitinib is included in the related NICE recommendation as it is recommended for CHE not AD. The TruE AD studies didn't evaluate chronic hand eczema outcome. And this outcome isn't in the listed outcome measures to be considered.</p> <p>There may be some value in referring to the most up to date European guidelines for reference, as the UK guideline hasn't been updated for some time. Our discussions with health care professionals suggests the European</p>	Thank you for your comment. NICE technology appraisal 1107, delgocitinib for treating moderate to severe chronic hand

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		Guideline (EuroGuiDerm) on atopic eczema: Living update3 is referenced most often.	eczema has been removed.
	British Association of Dermatologists (professional)	The economic analyses must include the number/frequency of hospital visits, blood tests and other investigations, and whether treatment could be initiated in primary care by Advice & Guidance or followed up in primary care, to reduce burden on secondary care centres.	Thank you for your comment. The scope is intended to provide a very brief summary of the appraisal. Further data and information will be discussed by committee following input from the company submission, clinical experts and patient groups. No action required.
	Eczema Outreach Support (patient group)	Ruxolitinib could be considered a candidate for managed access if it were introduced in primary care settings on a trial basis. This would enable data collection on real world uptake, prescribing patterns and patient outcomes. In particular, it would allow assessment of whether introducing an more advanced therapy in primary care improves overall access to such treatments, or whether barriers to accessing advanced therapies persist despite its availability. It would also help determine whether the treatment delivers meaningful clinical benefits for people with AD compared with existing primary care options.	Thank you for your comment. The committee will consider any managed access proposals submitted by the company alongside the managed access criteria.
	Eczema UK (Formerly National Eczema)	Eczema UK encourages NICE to consider the broader lived experience and treatment burden associated with moderate atopic dermatitis, including the	Thank you for your comment. Further data and information relating to treatment burden and

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	Society; patient group)	<p>significant psychological, social and functional impacts that may not always be fully captured through conventional clinical severity measures.</p> <p>The organisation believes the evaluation should consider:</p> <ul style="list-style-type: none"> • the cumulative burden of chronic itch, sleep disturbance and recurrent flares; • the impact of eczema on mental health, confidence, social participation, employment and education; • treatment burden associated with long-term topical therapy use, including time required for application, adherence challenges and concerns regarding prolonged topical corticosteroid use; • the fluctuating and relapsing nature of eczema, including the importance of maintaining disease control over time; • the importance of patient choice and acceptability of different treatment approaches within the care pathway. <p>Eczema UK also encourages NICE to consider how ruxolitinib may be used in real-world clinical practice, particularly for people whose eczema is inadequately controlled with existing topical treatments but who may not yet be eligible for systemic or biologic therapies.</p> <p>The organisation additionally welcomes consideration of outcomes in people with skin of colour and supports inclusion of evidence that reflects diversity in disease presentation and patient experience across different populations.</p>	quality of life will be discussed by committee during the appraisal following input from the company submission, clinical experts and patient representatives.
Questions for consultation	Incyte Biosciences UK Limited (Company)	Where do you consider ruxolitinib will fit into the existing care pathway for moderate atopic dermatitis?	Thank you for your comment. No action required.

		<p>D. Other</p> <p>Ruxolitinib cream is expected to be initiated and prescribed within a secondary care-led dermatology service. Routine follow-up is also expected to be secondary care-led initially, supporting dermatology oversight and implementation of the patient access scheme. Over time, where appropriate and locally feasible, some aspects of follow-up may be delivered in community-based settings, for example through dermatology outreach services or local shared care arrangements. This reflects the topical route of administration of ruxolitinib cream, its use in routine dermatology practice, and the expectation that it can be managed with dermatology oversight without intensive routine monitoring, while also supporting implementation of the patient access scheme.</p> <p>Would ruxolitinib be a candidate for managed access?</p> <p>Incyte does not currently anticipate that managed access would be required for ruxolitinib. This is because ruxolitinib has been studied in a substantial clinical trial programme, including phase 3 studies, and Incyte expects the available clinical evidence to support a routine NICE appraisal without the need for further evidence generation through managed access.</p> <p>Do you consider that the use of ruxolitinib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?</p> <p>Incyte anticipates that the QALY calculation may capture some, but not all, of the health-related quality of life (HRQoL) and economic-related benefits of ruxolitinib cream in AD.</p> <p>Wider societal and patient-incurred costs are not included in the NICE reference case, which adopts an NHS and Personal Social Services perspective. This is relevant in AD, where symptoms may affect work productivity and usual activities (24), and patients may incur out-of-pocket costs related to disease management and healthcare attendance (25).</p> <p>AD is also associated with substantial impairment in HRQoL affecting nearly every facet of daily living, including social functioning, emotional and mental</p>	
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		<p>wellbeing, daily activities, and sleep (24, 26-29). Although EQ-5D is the preferred measure for estimating HRQoL in NICE technology appraisals, it may not fully capture disease-specific impacts in dermatological conditions, including AD (30, 31). This is reflected by ongoing research into skin-related EQ-5D bolt-ons, including concepts such as skin irritation, self-confidence, and sleep (32). Therefore, some benefits of ruxolitinib relating to itch, sleep disturbance, psychological burden, and daily functioning may not be fully captured in the QALY calculation.</p> <p>Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.</p> <p>Data that will enable the committee to take account of these benefits will be derived from the pivotal phase 3 trial supporting the submission, TRuE-AD4, which included endpoints capturing pruritus, sleep disturbance, anxiety and depression, and work productivity outcomes.</p> <p>Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.</p> <p>Conventional systemic immunosuppressants (azathioprine, ciclosporin, methotrexate, and mycophenolate mofetil) have historically been used for patients with AD whose disease is inadequately controlled with topical therapy (21, 37, 38). With the exception of ciclosporin, these agents are used off-label in UK clinical practice. They are typically initiated in secondary care and require baseline screening and ongoing laboratory monitoring due to the risk of systemic adverse effects. Their use may be constrained by tolerability issues, safety considerations, and limits on treatment duration (39-41).</p>	
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		<p>Ciclosporin is licensed in the UK only for the treatment of severe AD; however, its use is associated with nephrotoxicity, hypertension, and metabolic adverse effects (e.g. hyperlipidaemia, hypertrichosis) (40). Current guidelines recommend restricting ciclosporin to short-term use (≤ 12 months) because of cumulative toxicity, and regular monitoring of blood pressure and renal function is required (41).</p> <p>As a result, dosing regimens for conventional systemic immunosuppressants in clinical practice vary and are generally informed by specialist clinical judgement.</p>	
	LEO Pharma (comparator)	N/a	No action required
	Pfizer Ltd (comparator)	<p>Where do you consider ruxolitinib will fit into the existing care pathway for moderate atopic dermatitis?</p> <p>Clinicians and commissioners of AD services would be best placed to answer this and will also depend on its anticipated label. However, given its vitiligo indication it seems reasonable that this would be prescribed in C) secondary care with routine follow up in secondary care for consistency.</p> <p>For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.</p> <p>Addressing comments on population and comparators will dictate the setting and follow up. Clinicians and commissioners of AD services would be best placed to answer this</p> <p>Would ruxolitinib be a candidate for managed access?</p>	

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		Potentially, if more evidence is required to address substantial uncertainties in the evidence submitted.	
	British Association of Dermatologists (professional)	<p>Where do you consider ruxolitinib will fit into the existing care pathway for moderate atopic dermatitis?</p> <p><input type="checkbox"/> Between first-line topical therapy and first-line conventional systemic immunomodulatory therapy.</p> <p>Please select from the following, will ruxolitinib be:</p> <p>A. Prescribed in primary care with routine follow-up in primary care</p> <p>B. Prescribed in secondary care with routine follow-up in primary care</p> <p>C. Prescribed in secondary care with routine follow-up in secondary care</p> <p>D. Other (please give details):</p> <p>For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.</p> <p><input type="checkbox"/> The setting for prescribing and routine follow-up for the comparators and subsequent treatments would differ slightly from that for the intervention, in that conventional systemic immunomodulatory therapy will need to be</p>	Thank you for your comment. No action required

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		<p>initiated in secondary care but can be followed up in primary care via shared care arrangements.</p> <p>Would ruxolitinib be a candidate for managed access?</p> <p><input type="checkbox"/> Possibly.</p> <p>Do you consider that the use of ruxolitinib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?</p> <p><input type="checkbox"/> Yes, QALY is a blunt tool for measuring health-related benefits in skin disease. Return to normal employment & reduction in sick days (occupational benefits), stigma due to disease visibility, daily/family responsibilities, improved school attendance, reduced anxiety resulting from ongoing requirement for TCS therapy (common occurrence in patients where TCS are not fully effective), etc. may be undercounted financial benefits.</p> <p>Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.</p> <p>Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.</p>	

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	Eczema Outreach Support (patient group)	N/a	No action required
	Eczema UK (Formerly National Eczema Society; patient group)	<p>Eczema UK considers that ruxolitinib is likely to sit between conventional topical therapies and escalation to systemic or advanced therapies within the current treatment pathway. It may be particularly relevant for people with moderate atopic dermatitis whose condition is inadequately controlled with emollients, topical corticosteroids and/or topical calcineurin inhibitors, but who may not yet be candidates for systemic immunosuppressants, biologics or oral JAK inhibitor treatment.</p> <p>The organisation anticipates that prescribing may initially occur primarily within intermediary/secondary care or specialist dermatology services, particularly during early implementation, although routine follow-up may subsequently involve primary care in some cases depending on local service arrangements and prescribing pathways.</p> <p>Eczema UK believes it is important that the evaluation fully captures patient-important benefits that may not always be adequately reflected within standard QALY calculations alone. These may include improvements in itch, sleep, visible skin symptoms, confidence, social participation, mental wellbeing and reduction in treatment burden. The impact of eczema on day-to-day functioning can be substantial even in people categorised as having moderate disease.</p> <p>The organisation also encourages NICE to consider the remitting/relapsing nature of eczema and the importance of maintaining long-term disease control, treatment adherence and patient acceptability when evaluating effectiveness and value within the NHS care pathway.</p>	Thank you for your comment. No action required

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Additional comments on the draft scope	Incyte Biosciences UK Limited (Company)	N/a	No action required
	LEO Pharma (comparator)	N/a	No action required
	Pfizer Ltd (comparator)	No additional comments	No action required
	British Association of Dermatologists (professional)	If the population covered by this STA includes children aged 2 years and above, NICE guideline CG57 https://www.nice.org.uk/guidance/cg57 should be listed in the 'Related NICE guidelines' section in the table.	Thank you for your comment. The population and remit have been updated to reflect the anticipated marketing authorisation. Subsequently, this NICE guideline is not relevant and has not been included in the scope. No action required.
	Eczema Outreach Support (patient group)	N/a	No action required

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	Eczema UK (Formerly National Eczema Society; patient group)	<p>Eczema UK welcomes the inclusion of patient-centred considerations within the draft scope, particularly the focus on itch, quality of life and skin colour subgroups. The organisation believes it is important that the evaluation reflects the real-world burden of moderate atopic dermatitis and recognises that substantial unmet need can exist even among people who may not be eligible for systemic or advanced therapies.</p> <p>Eczema UK encourages NICE to ensure that the appraisal gives appropriate weight to patient-reported outcomes and lived experience alongside clinician-assessed severity measures. Traditional severity classifications may not always capture the full impact of eczema on sleep, mental health, social functioning, work, education and family life.</p> <p>The organisation also encourages consideration of how ruxolitinib may fit within the evolving treatment landscape for atopic dermatitis, including its potential role as an additional option before escalation to systemic therapies.</p> <p>Finally, Eczema UK welcomes NICE's inclusion of equality considerations within the draft scope and strongly encourages continued attention to disparities affecting people with skin of colour and others who may experience barriers to timely diagnosis, severity assessment or access to specialist care.</p>	Thank you for your comment. No action required.