National Institute for Health and Care Excellence

Health Technology Evaluation

Delgocitinib for treating moderate to severe chronic hand eczema [ID6408]

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

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Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	LEO Pharmaceuticals	LEO Pharma confirm agreement that this is a suitable topic for a Single Technology Appraisal process.	Thank you for your comment. No action required.
	British Association of Dermatologists	Yes, it is appropriate.	Thank you for your comment. No action required.
	National Eczema Society	Yes, it is appropriate for NICE to evaluate this topic as a single technology appraisal. This is a new type of drug for treating chronic hand eczema.	Thank you for your comment. No action required.
	Allergy UK	Current treatments for chronic hand eczema are limited and have limited efficacy. New treatment options are needed urgently for patients who are suffering.	Thank you for your comment. No action required.
Wording	LEO Pharmaceuticals	LEO Pharma 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.

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	British Association of Dermatologists	Yes, it is reasonable. There is a group of patients who might require long-term immunosuppressive therapy due to the severity, chronicity and other effects of their hand dermatitis on aspects of their lives, such as their occupation.	Thank you for your comment. No action required.
	National Eczema Society	Yes, we believe 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.
	Allergy UK	The wording is predominantly focussed on the physical entity of the disease and doesnt bring in with enough emphasis the potential psychological impact that many people with eczema experience. Chronic hand eczema has the potential to significantly impact on a persons physical and psychological wellbeing. Hand eczema goes beyond the visible and distressing physical symptoms associted with this disease e.g. dry,itchy, red and cracked hands. The pschological impact that chronic hand eczema can have has the potential to impact upon many other aspects of daily life. Adults affected by hand eczema may have to change occupation or job roles because of the work they do which may result in loss of earnings and the ability to pursue a career that they have trained and/or studied for. With the hands being a visible part of the body there are issues around social stigma and for the individual feelings of anxiety and embarrasment. Avoidance of social situations can lead to loneliness and social isolation.For some people the chronic natutre of the disease may lead to depression requiring medication and other interventions which have cost implications for the Health Care sytstems.	Thank you for your comment. The wording of the remit has been retained, while the background section of the scope has been amended to reference the impact of hand eczema on mental well-being.
Timing issues	LEO Pharmaceuticals	The proposed scheduling of this appraisal is appropriate relative to the target date of MHRA approval. Delgocitinib is a topical medication, which will be the first novel medicine approved specifically for the treatment of moderate to severe chronic hand eczema (CHE). The only licensed treatment for CHE is	Thank you for your comment. This topic has been scheduled into NICE's work

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		alitretinoin, specifically for severe CHE only, which was positively recommended by NICE in 2009.	programme. For further details, please see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11506 No action required.
	British Association of Dermatologists	There is an increasing number of patients who are hesitant and/or concerned about the use of topical corticosteroids, and healthcare professionals (including those in primary care) may also have similar concerns; therefore, non-steroid topical treatment options would be welcome, particularly for patients who do not wish to have systemic or phototherapy, or if these are difficult to tolerate/adhere to, or are contraindicated	Thank you for your comment. This topic has been scheduled into NICE's work programme. For further details, please see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11506 No action required.
	National Eczema Society	Current treatments for chronic hand eczema are limited and have limited efficacy. New treatment options are needed urgently for patients who are suffering.	Thank you for your comment. This topic has been scheduled into NICE's work programme. For further details, please see the NICE website: https://www.nice.org.uk/

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			guidance/indevelopment/gid-ta11506 No action required.
	Allergy UK	Hand eczema is challenging to treat due to inflammation and recurring flares and the need for long term specialist management which itself can be difficult for people due to inequalities in service access and demand on dermatology appointments from competing conditions leading to long waiting lists and delayed treatment. Beyond potent topical steroids and immunosupressants there are very limited treatent options that available for clinicians to chose from and access to these are limited to who is seen in what setting e.g. Primary Versus Secondary care. The availability of another treatent choice that people can self administer at home would allow for significant improvements in the current standard of care and give people with hand eczema greater autonomy over their condition.	Thank you for your comment. This topic has been scheduled into NICE's work programme. For further details, please see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11506 No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	LEO Pharmaceuticals	LEO Pharma would like to suggest some changes to the background information as outlined below: First Paragraph LEO Pharma proposes that the term "and painful" should be added after "dry, itchy, cracked".	Thank you for your comment. The background section of the scope has been amended to include the word "painful" in the description of hand eczema, and to include The scope has also

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		Second paragraph LEO Pharma proposes that the wording should be amended to the following, to capture the relevant definitions and causes of CHE: Hand eczema can be referred to as acute or chronic. Acute hand eczema can be defined as eczema, localised to the hands, which lasts for less than 3 months and does not occur more than once per year. Whilst CHE refers to hand eczema that lasts for more than 3 months or where acute flares relapse or recur twice or more per year[1]. Hand eczema is a multifactorial disease that can be commonly classified by its underlying cause. The three most common causes are irritant contact dermatitis (ICD), allergic contact dermatitis (ACD) and atopic hand eczema. Often, more than one underlying cause plays a role in the development of the disease, for example ICD is often alongside ACD and atopic hand eczema. It is difficult to draw definitive conclusions about the underlying cause of an individual patient's hand eczema, as this may evolve over time. Hand eczema affects around 10% of the general population and up to 30% of people in high-risk occupational groups such as healthcare workers. Between one third and one half of hand eczema cases are moderate or severe. The technology LEO Pharma suggest that the word "placebo" be changed to "cream vehicle". Additionally, LEO Pharma suggest that the wording "for whom topical corticosteroids are not advisable" be replaced with "for whom treatment with topical corticosteroids is inadequate or inappropriate"	been amended to include the definition of chronic hand eczema as defined by the European Society of Contact Dermatitis. The technology section of the scope has been amended to replace the word "placebo" with "cream vehicle" and to reference a further study comparing delgocitinib with alitretinoin in adults with severe chronic hand eczema that has not responded to treatment with topical corticosteroids or for whom topical corticosteroids are inadequate or inappropriate.

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		LEO Pharma would also like to include an additional study within this section, described as follows: "A further study explored the relative effectiveness of delgocitinib compared to alitretinoin in severe chronic hand eczema that has not responded to treatment with topical corticosteroids or for whom treatment with topical corticosteroids is inappropriate.[2] The study was done within the population for which alitretinoin is indicated, severe CHE that has not responded to treatment with topical corticosteroids." References: 1. Agner & Elsner (2020) Hand eczema: epidemiology, prognosis and prevention. Journal of the European Academy of Dermatology and Venereology 34(1): p4-12 Hand eczema: epidemiology, prognosis and prevention - PubMed (nih.gov) 2. LEO (Study completed Dec 2023), NCT05259722	
	British Association of Dermatologists	The importance of patch testing chronic hand eczema is missing which could be featured after the sentences, *"The condition can be classified into atopic hand eczema, caused by genetic or endogenous factors, and contact dermatitis which is caused by exposure to irritants or allergens. Hand eczema may also be caused by a combination of these elements."*	Thank you for your comment. The background section of the scope has been amended to include reference to the use of patch testing to identify allergens contributing to chronic hand eczema.
	National Eczema Society	The background information appears to be accurate. For avoidance of doubt and for completeness, we think pompholyx eczema should be mentioned	Thank you for your comment. The

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		specifically as a cause of hand eczema, and also both irritant contact dermatitis and allergic contact dermatitis.	background section of the scope has been amended to include information on pompholyx eczema.
	Allergy UK	The background section would benefit from including information on disease impact and the psychological issues mentioned in the previous sections.	Thank you for your comment. The background section of the scope has been amended to reference the impact of hand eczema on mental well-being.
Population	LEO Pharmaceuticals	LEO Pharma suggest that the phrase “not advisable” be replaced by “inadequate or inappropriate” such that a revised population definition would read: “Adults with moderate to severe chronic hand eczema that have not responded to treatment with topical corticosteroids or for whom topical corticosteroids are inadequate or inappropriate“	Thank you for your comment. The population in the scope has been amended to “Adults with moderate to severe chronic hand eczema that has not responded to treatment with topical corticosteroids or for whom topical corticosteroids are inadequate or inappropriate.”

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	British Association of Dermatologists	Yes, however, consider including pre-treatment of irritant contact dermatitis and assessment/treatment of allergic contact dermatitis.	Thank you for your comment. No action required.
	National Eczema Society	Yes. Hand eczema is relatively common in the UK. The hand eczema information is among the most viewed content on the National Eczema Society website - https://eczema.org/information-and-advice/types-of-eczema/hand-eczema/	Thank you for your comment. No action required.
Subgroups	LEO Pharmaceuticals	The first two subgroups noted (atopic vs contact CHE and moderate vs severe disease) are recognised as appropriate. The third subgroup outlined in the draft scope (inadequate response to TCS vs TCS not advisable) suggests that a subgroup analysis could be explored to examine the effects of treatment in patients who have had an inadequate response to TCS compared with those who are not eligible for treatment with TCS. In DELTA 1 and DELTA 2, the pivotal trials for delgocitinib versus cream vehicle – 99% of patients across both arms had an inadequate response to TCS in the last 12 months and 20.3% of patients across both treatment arms were inappropriate for treatment with TCS. This means that there is a significant overlap between these two populations within the key clinical studies. Therefore, subgroup analyses based on ineligibility for TCS versus inadequate response to TCS would not provide a meaningful comparison regarding the relative clinical efficacy of delgocitinib in these two subgroups. LEO Pharma suggest that this subgroup be removed from the scope accordingly.	Thank you for your comment. The subgroups are kept inclusive in the scope to avoid excluding any relevant subgroups. Stakeholders will have the opportunity to justify exclusion of subgroups at the appraisal stage. No action required.

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	British Association of Dermatologists	Agree with the draft scope, i.e.: • Primary cause of hand eczema (atopic or contact) • Moderate vs. severe disease Inadequate response to topical corticosteroids vs. topical corticosteroids not advisable	Thank you for your comment. No action required.
	National Eczema Society	We agree the suggested subgroups are appropriate, subject to ensuring these including people with chronic hand eczema related to pompholyx eczema, irritant contact dermatitis and allergic contact dermatitis.	Thank you for your comment. No action required.
Comparators	LEO Pharmaceuticals	Delgocitinib is intended to be positioned as a second-line treatment in the existing care pathway for moderate to severe CHE. Defining the comparator set for delgocitinib is complex due to a lack of clear guidelines, a paucity of clinical evidence for unlicensed treatments and a disparity in local practice. Alitretinoin, recommended for second-line use, is the only licenced treatment for severe CHE. A wide variety of treatments are used off-label for both moderate and severe CHE, due to the lack of licenced long-term treatment options. There are no UK-specific treatment guidelines for CHE, so clinicians may refer to the European Society of Contact Dermatitis (ESCD) guidelines[3]. Within the ESCD guidelines, alitretinoin is recommended as a 2nd line treatment after TCS for severe CHE, with an evidence grading of “A”. LEO Pharma supports its inclusion as a comparator to delgocitinib.	Thank you for your comment. The comparators are kept broad in the scope to avoid excluding any potentially relevant comparators. No action required.

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		PUVA is “suggested” within ESCD Guidelines for those patients who are refractory to TCS or in whom treatment with TCS are inappropriate. LEO Pharma supports its inclusion as a comparator to delgocitinib. Within the ESCD guidelines, systemic immunosuppressants are positioned in CHE patients who are refractory or contraindicated to 1st and 2nd line options and therefore are positioned at a different point in the treatment pathway. In addition, methotrexate and azathioprine have the lowest grade of recommendation. We propose that methotrexate and azathioprine should be excluded as comparators in the scope, given the lower grade rating within the ESCD guidelines and lack of data to conduct any meaningful comparison. Mycophenolate mofetil is not included in the ESCD guidelines and should therefore not be considered. <u>Atopic dermatitis treatments in CHE</u> CHE and AD are distinct conditions. CHE has a more heterogenous pathophysiology than AD, involving different immune signatures. Therefore, patients with CHE should ideally receive targeted treatment. However, the absence of alternative options means treatments approved for AD may on occasion be used off-label for non-atopic CHE.	
	British Association of Dermatologists	Topical corticosteroids, topical calcineurin inhibitors and narrowband UVB should also be included as comparators.	Thank you for your comment. The population in this scope is for people who have not responded to or for whom topical corticosteroids are

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			inappropriate, so topical corticosteroids have not been added to the list of comparators. Topical calcineurin inhibitors and narrowband UVB have been added as comparators to the scope.
	National Eczema Society	Yes, to our knowledge these are comparator treatments for moderate to severe chronic hand eczema in the NHS. Patients being treated in primary care would not typically have access to systemic treatments, which are usually initiated and monitored in secondary care. Accessing ultraviolet light therapy (PUVA) can be difficult/unviable for patients who are working because of travel times to the hospital and the need for multiple therapy sessions per week over three months or longer.	Thank you for your comment. The point raised about access to treatments has been addressed in the Equality Impact Assessment of the scope.
Outcomes	LEO Pharmaceuticals	The outcome measures to be considered include: • measures of disease severity (Investigator's Global Assessment for Chronic Hand Eczema [IGA-CHE] treatment success [TS], Hand Eczema Severity Index [HECSI]-75, HECSI-90 and HECSI score reduction)	Thank you for your comment. The scope has been amended to remove 'disease free period/maintenance of

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		• measures of symptom control, including improvement in itch (Hand Eczema Symptoms Diary [HESD]-PAIN and HESD-ITCH) • disease free period/maintenance of remission • time to relapse/prevention of relapse (Time to first IGA-CHE score ≥2) • adverse effects of treatment • health-related quality of life (Dermatology Life Quality Index [DLQI] >4 point improvement data, area under the curve change from baseline in DLQI and EQ-5D). We consider that the treatment outcomes 'disease free period/maintenance of remission' and 'time to relapse/prevention of relapse' are identical in the way that they would be measured. Therefore, we suggest that disease free period/maintenance remission be removed. LEO Pharma would like to highlight that according to our DELTA 3 protocol "time to relapse data" is represented by patients who fall out of the trial definition of treatment success (IGA-CHE score ≥2) however, this does not necessarily mean that patients have regressed to their baseline severity score of moderate or severe (IGA-CHE 3 or 4).The primary endpoint in the DELTA 1 and DELTA 2 studies was IGA-CHE TS. Key secondary endpoints in DELTA 1 and DELTA 2 were HECSI-75, HECSI-90 and percentage change in HECSI score from baseline. The primary endpoint in the DELTA 3 study was number of treatment-emergent adverse events. Key secondary endpoints were IGA-CHE, HECSI-75 and HECSI-90. The primary endpoint in the DELTA FORCE study was change in HECSI score from baseline. Key secondary endpoints were IGA-CHE treatment success, HECSI-90, HESD-PAIN, HESD-ITCH and area under the curve change from baseline in DLQI.	remission' from the outcomes section of the scope. The outcomes included in the scope do not include specific measures or indexes for each outcome.

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	British Association of Dermatologists	The outcomes listed are appropriate.	Thank you for your comment. No action required.
	National Eczema Society	Yes, the suggested outcome measures are important health-related benefits (and harms) of delgocitinib. We would like to see outcomes fully reflect patient experience – using measures like the Patient Oriented Eczema Measure (POEM). Patients say chronic hand eczema can have a huge impact on their ability to do everyday tasks and can affect their ability to work and study, among other things. We use our hands as a form of communication too and they are almost always on show – and so chronic hand eczema can disproportionately impact patients' mental health and emotional well-being. A patient experience measure would capture these different impacts. It should be noted that certain measures of disease severity like EASI are more challenging to apply in chronic hand eczema, which affects a relatively small area of the body, but can be hugely debilitating both physically and emotionally.	Thank you for your comment. The outcomes included in the scope do not include specific measures or indexes for each outcome. Outcomes reflecting patient experience may be captured in the health-related quality of life outcome. No action required.
Equality	LEO Pharmaceuticals	The only licensed treatment for severe CHE is alitretinoin, which is associated with a teratogenicity risk. This means that patients who are able to become pregnant, would either be unsuitable for treatment with alitretinoin or would have to be involved in a pregnancy prevention programme. Therefore, patients having alitretinoin may experience tokophobia (fear of becoming pregnant). The potential adoption of delgocitinib which does not require a pregnancy prevention program, could provide women of childbearing age with an alternative licensed treatment for CHE.	Thank you for your comment. The committee will take into account skin colour and how this could affect the assessment of the severity of chronic hand eczema

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		There is regional variation in the access to specialist services needed to deliver PUVA therapy. Even where access is available, some patients may be unable to access treatment due to the time and travel required to attend specialist healthcare settings e.g. if they are unable to get time off from work. This may exclude some people from treatment with PUVA. CHE may disproportionately affect patients who have co-morbidities, such as: HIV, Hepatitis B, Hepatitis C or other conditions that require antivirals as a primary treatment option. Antivirals are known to have many severe interactions which can increase the risk of drug toxicity or reduce the efficacy of a drug, when given in adjunction with systemic immunosuppressants. Due to this, patients with moderate to severe CHE who require antivirals to treat a condition have limited treatment options after TCS. Diagnosis of the severity of symptoms can be more difficult in people with brown and black skin. For example, reddening of skin (erythema) is more difficult to determine by visual assessment in people with brown and black skin. This means that some potential CHE patients with brown and black skin may be undiagnosed, which could lead to undertreatment. An intrinsically thinner stratum corneum and higher density of eccrine glands means that Asian people may have skin that is more sensitive to exogenous chemicals[4]. Some diagnostic tools, such as patch testing for allergic contact dermatitis, are not available in some locations. This results in inequality of diagnoses across different geographical locations within the UK.	and response to treatment. The committee will consider any potential equalities issues during the course of the appraisal.

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		CHE disproportionately impacts people in some job roles. For example, people who are involved in 'wet work', which is defined as a role which requires long lasting or repeated contact with water or other substances which can trigger CHE symptoms. This may include trade workers and people who work in the service industry, healthcare industry or education.	
	British Association of Dermatologists	Measures of disease severity, e.g. EASI, that include the assessment of erythema may underestimate the severity of disease in people with darker skin tones, where the severity of erythema can be less readily identified.	Thank you for your comment. The committee will take into account skin colour and how this could affect the assessment of the severity of chronic hand eczema and response to treatment.
	National Eczema Society	If delgocitinib can only be initiated by a dermatologist in secondary care, then treatment access is dependent on patients being under the care of a dermatologist. It should be noted chronic hand eczema can present differently on people with different skin tones, so accurate diagnosis, assessment and treatment is important for people of all skin tones.	Thank you for your comment. The committee will take into account skin colour and how this could affect the assessment of the severity of chronic hand eczema and response to treatment.

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			The committee will consider any potential equalities issues during the course of the appraisal.
Other considerations	National Eczema Society	Chronic hand eczema often affects people working in fields where frequent hand-washing is required, where there is routine exposure to chemicals and allergens, and where extensive wearing of gloves is required. The economic impact, for patients, their employers and the wider economy, of people needing time off work because of chronic hand eczema should be considered. Most patients with chronic hand eczema will be offered topical corticosteroids and, if these don't work well enough, some may be offered topical calcineurin inhibitors. Patients are becoming increasingly concerned about the safety and adverse effects of the long-term use of stronger topical corticosteroids that are typically prescribed for chronic hand eczema, especially the risk of topical steroid withdrawal (TSW) associated with using stronger steroids for long periods. The risk of skin infection is relatively high with chronic hand eczema and require antibiotic treatment.	Thank you for your comment. Information about the treatment pathway, increased risk of chronic hand eczema in high-risk occupational groups such as healthcare workers and the increased risk of infection are addressed in the background section of the scope. The committee will consider any potential equalities issues during the course of the appraisal.
	Allergy UK	Socio-econoic impact: The cost for peple living with chronic conditions with the current cost of living crisis and prescriptions in England for those eligible to pay being £9.90.	Thank you for your comment.

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		In addition to a loss of productivity and potential loss of earnings for individuals depending on their occupation and employer and whether they are self employed e.g. hair dressers.	As part of the technology appraisal, the committee will consider the impact of recommendations on people with protected characteristics in conjunction with the principles that guide the development of NICE guidance and standards including the aim to reduce heath inequalities. However. in accordance with NICE's social value judgement principles, no priority is given based on individuals' income, social class, position in life or social roles in guidance developed for the NHS.
Questions for consultation	LEO Pharmaceuticals	**Where do you consider delgocitinib will fit into the existing care pathway for moderate to severe hand eczema?** We anticipate that delgocitinib would be placed directly after TCS as a second-line treatment in the existing care pathway for moderate to severe chronic hand eczema.	Thank you for your comment. The committee will consider evidence submitted for any additional health related

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		Is there a difference in the way hand eczema is treated depending on the cause (atopic or contact)? No, there is no difference in the way that atopic and contact dermatitis are treated. But for contact dermatitis, removing potential trigger factors would be the first recommendation. Beyond this, the potential treatment received by patients would be the same for atopic and contact dermatitis. **Please select from the following, will delgocitinib be:** **A. Prescribed in primary care with routine follow-up in primary care** **B. Prescribed in secondary care with routine follow-up in primary care** **C. Prescribed in secondary care with routine follow-up in secondary care** **D. Other (please give details):** We expect that delgocitinib will be prescribed in secondary care, with routine follow-up in primary care (Option B). However, we accept that in clinical practice some patients may have follow-up in secondary care (Option C). **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.** Initial prescribing of alitretinoin and PUVA is done in secondary care and routine follow-up would also typically take place in secondary care. **Are there any other potential comparators specifically for hand eczema that has not responded to treatment with topical corticosteroids, or for people with hand eczema for whom topical corticosteroids are not advisable?** No additional treatments, outside of those included as comparators. **Would people with moderate to severe hand eczema be eligible for treatments for moderate to severe atopic dermatitis?**	benefits not captured in QALY calculations during the appraisal.

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		CHE and AD are distinct conditions. CHE has a more heterogenous pathophysiology than AD, involving different immune signatures. Therefore, patients with CHE should ideally receive targeted treatment. However, the absence of alternative options means treatments approved for AD may be used off-label for non-atopic CHE. **Are there any differences between the relevant comparators depending on whether hand eczema is moderate or severe?** Yes, the European guidelines have been outlined above, which detail the difference in treatment for patients with moderate and severe CHE **Would delgocitinib be a candidate for managed access?** Not applicable. **Do you consider that the use of delgocitinib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** There are significant costs associated with CHE from a patient perspective. For example, patients may need to take substantial time off work due to flare ups of symptoms and to attend appointments. During periods of flare ups, a large proportion of patients have also reported difficulty sleeping due to CHE. CHE also has a significant impact on personal relationships for patients, due to the psychological burden associated with the disease. Patients may also experience a reduction in the ability to contribute to household chores and take care of dependents, which further deteriorates the quality of personal relationships. Participation in general activities and hobbies is also affected. Data suggests that approximately 5% of patients studied have suicidal thoughts as a direct result of CHE symptoms[5].	

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		Patients receiving PUVA therapy need to travel to specialist healthcare settings to access treatment. This adds to patient burden, as people may need to take time off from work and caring responsibilities. Treatment with delgocitinib does not require routine visits to in-patient healthcare services, which will significantly reduce patients' out of pocket expenses. As highlighted in the equality section, the only licensed treatment for severe CHE is alitretinoin, which is associated with a teratogenicity risk. Therefore, patients having alitretinoin may experience tokophobia (fear of becoming pregnant). The use of delgocitinb would offer substantial benefit in this regard and this is unlikely to be captured in the QALY calculation. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** The company has conducted market research of 152 patients with CHE, which aims to quantify the impact on the patient's quality of life relating to a wide range of factors, such as physical and emotional wellbeing, personal relationships, ability to carry out daily activities and psychological impact. References: 3. Thyssen et al. (2022) Guidelines for diagnosis, prevention and treatment of hand eczema Guidelines for diagnosis, prevention, and treatment of hand eczema (wiley.com) 4. Chai et al. (2023) Are There Ethnic Differences in Hand Eczema? A Review. Journal of Clinical Medicine. 12(6):2232. 5. DOF DERM-001 June 2024 - Chronic Hand Eczema patient impact report, LEO Pharma Data on file.	

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	British Association of Dermatologists	**1. Where do you consider delgocitinib will fit into the existing care pathway for moderate to severe hand eczema?** An alternative or adjunct to topical to corticosteroids or topical calcineurin inhibitors, but at the same level of the treatment pathway. Even though topical treatments are considered prior to photo- and systemic therapy, they are often not discontinued throughout these therapeutic options. **2. Is there a difference in the way hand eczema is treated depending on the cause (atopic or contact)?** Contact dermatitis may be divided into irritant vs. allergic contact dermatitis; they may co-exist. The tendency to atopy may lower the threshold for contact dermatitis. Management of irritant contact dermatitis involves reduction of exposure to irritants, but avoidance of the allergen should be the aim in the management of allergic contact dermatitis. There is a place for topical treatments in all forms of hand dermatitis to reduce severity 1) prior to investigations such as patch testing (which should be performed), 2) if avoidance of allergens is difficult or 3) if reduction of exposure to irritants is inadequate or difficult to achieve. **3. Please select from the following, will delgocitinib be:** **A. Prescribed in primary care with routine follow-up in primary care** **B. Prescribed in secondary care with routine follow-up in primary care** **C. Prescribed in secondary care with routine follow-up in secondary care** **D. Other (please give details):** Prescribed in secondary care with routine follow-up in primary care. In the initial phase this will likely apply, similar to calcineurin inhibitors, as this delgocitinib is a topical agent.	Thank you for your comment. Comments related to comparators and equalities issues are addressed in previous consultation comments. The committee will consider evidence submitted for any additional health related benefits not captured in QALY calculations during the appraisal.

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		4. For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. Oral DMARD immunosuppressive drugs, oral JAK inhibitors and biological agents are commenced in secondary care. Alitretinoin involves pregnancy prevention program for those with child-bearing potential in secondary care. Phototherapy is also only applicable in secondary care. Use of DMARDs can be managed jointly with primary care if a shared-care agreement is in place. **5. Are there any other potential comparators specifically for hand eczema that has not responded to treatment with topical corticosteroids, or for people with hand eczema for whom topical corticosteroids are not advisable?** Both PUVA *and* narrowband UVB should be comparators, not just PUVA. **6. Would people with moderate to severe hand eczema be eligible for treatments for moderate to severe atopic dermatitis?** Yes. **7. Are there any differences between the relevant comparators depending on whether hand eczema is moderate or severe?** No, the comparators are relevant for both moderate and severe hand eczema. **8. Would delgocitinib be a candidate for managed access?**	

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		Possibly. **9. Do you consider that the use of delgocitinib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** Occupational benefits; reduction in sick days. **10. Equality** Measures of disease severity, e.g. EASI, that include the assessment of erythema may underestimate the severity of disease in people with darker skin tones, where the severity of erythema can be less readily identified.	

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

Neonatal and Paediatric Pharmacists Group