

National Institute for Health and Care Excellence

Health Technology Evaluation

Povorcitinib for treating moderate to severe active hidradenitis suppurativa

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	British Association of Dermatologists (BAD)	A single technology appraisal is appropriate.	Thank you for your comment. No action is needed.
	Incyte Biosciences UK,	Incyte agrees that the proposed evaluation of povorcitinib and the evaluation route (single technology appraisal) are appropriate.	Thank you for your comment. No action is needed.

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Wording	BAD	Yes.	Thank you for your comment. No action is needed.
	Incyte Biosciences UK	Incyte agrees with the current wording of the remit to appraise the clinical and cost effectiveness of povorcitinib for treating moderate to severe active hidradenitis suppurativa (HS) after a TNF-alpha inhibitor. The anticipated marketing authorisation of povorcitinib is: [REDACTED].	Thank you for your comments. No action is needed.
Timing Issues	BAD	High.	Thank you for your comment. This topic has been scheduled into the work programme and NICE aims to provide timely guidance to the NHS. No action is needed.
	Incyte Biosciences UK	The evaluation of povorcitinib is of high urgency to the NHS because of the substantial disease burden and limited treatment options for people whose disease is inadequately controlled with conventional therapies and a TNF-alpha inhibitor. HS is a chronic, painful inflammatory condition characterised	Thank you for your comments. This topic has been scheduled

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		<p>by recurrent abscesses, draining lesions and scarring, which can cause profound impairment in quality of life and is associated with high rates of depression and anxiety.¹ Many patients experience persistent disease activity despite currently available treatments and may require repeated courses of antibiotics, surgical procedures or hospital care. A systematic literature review conducted in 2023 reported that median time on treatment amongst patients treated with anti-TNF therapies was 11.9 months, the primary reason for treatment failure being development of anti-drug antibodies.^{2,3}</p> <p>A retrospective cohort study using Hospital Episode Statistics data, concluded that HS places a substantial burden on the UK healthcare system, with patients requiring frequent outpatient care, high rates of A&E attendance, and repeated inpatient admissions, leading to significant per-patient costs and a large overall societal economic impact.⁴</p> <p>The Office of Health Economics concludes that HS leads to substantial productivity losses in the UK, driven by work absence and reduced performance (with studies showing ~10–13% absenteeism, ~25–31% presenteeism, and ~30–34% overall work impairment), reflecting a major indirect economic burden.⁵</p> <p>Timely evaluation of povorcitinib would support access to the first oral JAK-inhibitor treatment in this patient population, which may help address the current unmet clinical need and reduce disease burden for patients and the NHS.</p> <ol style="list-style-type: none"> 1. Ingram JR, Bettoli V, Espy JI, Kokolakis G, Martorell A, Villani AP, et al. Unmet clinical needs and burden of disease in hidradenitis suppurativa: real-world experience from EU5 and US. <i>J Eur Acad Dermatol Venereol.</i> 2022;36(9):1597-605 2. Pham JP, Roseno NAL, Rocuzzo G, Saal RC, Egeberg A, Ring HC, et al. Drug survival of biologics in hidradenitis suppurativa: A systematic review and meta-analysis. <i>J Am Acad Dermatol.</i> 2024;91(1):170-2 	<p>into the work programme and NICE aims to provide timely guidance to the NHS. No action is needed.</p>

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		<p>3. Lu JD, Milakovic M, Piguat V, Alavi A. Antidrug antibodies to tumour necrosis factor inhibitors in hidradenitis suppurativa: a systematic review. Br J Dermatol. 2021 Mar;184(3):555-557</p> <p>4. Desai N, Shah P. High burden of hospital resource utilization in patients with hidradenitis suppurativa in England: a retrospective cohort study using hospital episode statistics. Br J Dermatol. 2017 Apr;176(4):1048-1055</p> <p>Office of Health Economics (2023) <i>The socioeconomic burden of hidradenitis suppurativa in the UK</i>. London: Office of Health Economics</p>	

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Incyte Biosciences UK	Incyte agrees that the data presented in the background information accurately reflects the treatment pathway for patients with HS in England and Wales.	Thank you for your comment. No action is needed.

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Population	BAD	Yes.	<p>Thank you for your comment. No action is needed.</p> <p>Please note, we have amended the definition to include “People with moderate to severe HS where TNF-alpha inhibitor is not suitable, did not work or has stopped working”.</p>
	Incyte Biosciences UK	Incyte would like to amend the wording of the Population to “Adults with moderate to severe HS where adalimumab is not suitable, did not work or has stopped working”	<p>Thank you for your comment. We have amended the definition to include “People with moderate to severe HS where TNF-alpha inhibitor is not suitable, did not work or has stopped working”.</p>

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Subgroups	BAD	No, we do not currently have agreed sub-phenotypes of HS or specific sub-populations who should be considered separately.	Thank you for your comment. No action is needed.
	Incyte Biosciences UK	No subgroups have been suggested in the scope. Incyte believes this is appropriate.	Thank you for your comment. No action is needed.
Comparators	BAD	Yes, secukinumab is an appropriate comparator as bimekizumab has not been approved by NICE for HS.	Thank you for your comment. No action is needed. Please note “Best supportive care” was added for completeness.
	Incyte Biosciences UK	Incyte agrees that secukinumab is the only appropriate comparator for povorcitinib in its anticipated positioning, as stated in the draft scope. <ul style="list-style-type: none"> • Should best supportive care be included as a comparator? Incyte does not believe that best supportive care (BSC) should be included as a comparator for two reasons:	Thank you for your comments. “Best supportive care” was added for completeness.

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		<p>1. The proportion of patients in whom best supportive care would be relevant is very small. BSC would only be used in the target population when secukinumab is contraindicated. Contraindications specific to secukinumab (i.e. which do not also apply to povorcitinib) are limited to hypersensitivity to secukinumab or its excipients and inflammatory bowel disease.</p> <p>Feedback from clinical opinion leaders also suggests BSC is composed of a heterogenous set of treatments options which can include continuation of biologic treatments (despite suboptimal response) and enrolment in clinical trials. The British Association of Dermatologists has also previously stated that BSC is difficult to define and is insufficient to prevent disease progression in those with moderate-to-severe HS, allowing progressive scarring to occur. Robust estimation of cost-effectiveness against BSC would be challenging due to the small proportion of contraindicated patients represented in trial populations and poor alignment between treatments received in the placebo arm of trials and real-world BSC treatment.</p>	
Outcomes	BAD	<p>The Hidradenitis Suppurativa Core Outcomes Set International Collaboration (HISTORIC) has defined six core outcome domains to measure in HS trials: pain, health-related quality of life, physical signs, global assessment (patient & physician), disease progression (flare frequency/time to recurrence), and other symptoms (drainage & fatigue) (Thorlacius <i>et al.</i> 2018, https://doi.org/10.1111/bjd.16672).</p>	<p>Thank you for your comments.</p> <p>We have updated the outcomes list to encompass the core domains included in Thorlacius 2018, for</p>

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			<p>outcomes not listed in the draft scope.</p> <p>Please note that this is not an exhaustive list and any relevant outcomes can be included in the submissions.</p>
	Incyte Biosciences UK	Incyte agrees that the proposed outcomes are appropriate.	<p>Thank you for your comment. No action is needed.</p> <p>Please note we have updated the outcomes list to encompass the core domains included in Thorlacious 2018.</p>
Equality	BAD	<p>Probable higher incidence in people of African descend and in those from lower socioeconomic background (https://doi.org/10.1001/jamadermatol.2025.1190), have been correctly</p>	<p>Thank you for your comment. These equalities considerations are formally addressed in</p>

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		identified. Please bear in mind that peak prevalence (2%) is in females of child-bearing age.	the Equalities Impact Assessment form.
	Incyte Biosciences UK	No equality issues are foreseen if povorcitinib were to be recommended for use for all patients at the anticipated positioning.	Thank you for your comment. No action is needed.
Other considerations	BAD	Prevention of disease progression in HS is important because it is a scarring condition. The scarring limits function, which in turn limits ability to work and study. Reversal of scarring may require extensive surgery, for example axillary surgery healing times are about 3 months for wide excision and for the groin and buttocks may exceed 6 months. Scarring also contributes to the mental health burden of HS, as patients can experience stigma due to the effects on their appearance.	Thank you for your comments. The evidence for povorcitinib will be considered during the evaluation. The impact of potential stigma will be considered on the Equality Impact Assessment form. No action is needed.
	Incyte Biosciences UK	No comment.	-

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Questions for consultation	BAD	<p>Where do you consider povorcitinib will fit into the existing care pathway for moderate to severe active hidradenitis suppurativa?</p> <ul style="list-style-type: none"> • Do you anticipate that povorcitinib will be used at the same place of the pathway as secukinumab - where adalimumab is not suitable, did not work or has stopped working? Yes. • Should best supportive care be included as a comparator? Best supportive care is difficult to define (perhaps doxycycline should be considered here) and is insufficient to prevent disease progression in those with moderate-to-severe HS, allowing progressive scarring to occur. • If evidence allows, should results be presented separately for moderate and severe hidradenitis suppurativa subgroups? https://onlinelibrary.wiley.com/doi/10.1111/bjd.17537 In moderate disease, as defined by Hurley staging and the IHS4 classification, scarring is already occurring and so it is best to consider the two subgroups together to prevent progression and treat to target (https://doi.org/10.1093/bjd/ljaq041). <p>Please select from the following, will povorcitinib be:</p> <ol style="list-style-type: none"> 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. <u>Prescribed in secondary care with routine follow-up in secondary care</u> D. Other (please give details): 	<p>Thank you for your comments.</p> <p>Please note “Best supportive care” was added for completeness.</p> <p>Please note we have updated the outcomes list to encompass the core domains included in Thorlacious 2018.</p>

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		<p>For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. It does not differ.</p> <p>Would povorcitinib be a candidate for managed access? Possibly. A British Association of Dermatologists-supported UK registry for HS, H-STRONG, was set up 2024, which should provide UK real world evidence.</p> <p>Do you consider that the use of povorcitinib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? Povorcitinib will provide a step-change in HS management, as the first Janus kinase inhibitor (JAKi) therapy available for HS and a much-needed alternative to biologics for the quite high proportion of HS patients exhibiting adalimumab and secukinumab primary or secondary failure. Patients' expectations now exceed the 50% improvement in inflammatory lesions denoted by the HiSCR trial endpoint and only 50% of HS patients reached even this endpoint in the adalimumab PIONEER studies (https://doi.org/10.1056/NEJMoa1504370) and secukinumab SUNRISE and SUNSHINE trials (https://doi.org/10.1016/S0140-6736(23)00022-3). In both cases, median treatment survival of adalimumab and secukinumab is less than one year, (https://doi.org/10.1093/bjd/ljae042) in the context of a chronic disease with onset in early adulthood needing treatment for multiple decades. Prevention of disease progression and subsequent scarring is very important and so options to allow treatment switching due to insufficient response to</p>	

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		<p>adalimumab are vital to prevent disease progression, which in turn causes greater impact on patients and the NHS.</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 see references provided in the section above.</p>	
	Incyte Biosciences UK	<p>Where do you consider povorcitinib will fit into the existing care pathway for moderate to severe active hidradenitis suppurativa?</p> <ul style="list-style-type: none"> Do you anticipate that povorcitinib will be used at the same place of the pathway as secukinumab - where adalimumab is not suitable, did not work or has stopped working? <p>Yes, Incyte anticipates that povorcitinib will be used as an alternative option at the same place in the pathway as secukinumab.</p> <ul style="list-style-type: none"> Should best supportive care be included as a comparator? <p>No, for the reasons stated above in the “Comparators” section.</p> <ul style="list-style-type: none"> If evidence allows, should results be presented separately for moderate and severe hidradenitis suppurativa subgroups? <p>Multi-level network meta-regression analyses suggest that relative effectiveness of treatments is not associated with disease severity (as measured by IHS4 score).</p> <p>The clinical trials for povorcitinib are not sufficiently powered to allow for a robust subgroup analysis of patients with moderate and severe disease separately in the population previously treated with an anti-TNF inhibitor. In addition, data are not presented separately for these subgroups in the</p>	<p>Thank you for your comments.</p> <p>Please note “Best supportive care” was added for completeness.</p> <p>Please note we have updated the outcomes list to encompass the core domains included in Thorlacious 2018.</p>

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		<p>comparator trials to enable an Indirect Treatment Comparison to be conducted.</p> <p>Please select from the following, will povorcitinib 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>Incyte expects povorcitinib to be prescribed in secondary care with routine follow-up in secondary care in the same way as secukinumab.</p> <p>Would povorcitinib be a candidate for managed access?</p> <p>Given the availability of direct evidence from two large, identically designed, head-to-head comparison trials (STOP-HS1 and STOP-HS2 in 608 and 619 patients respectively) Incyte does not consider it appropriate for povorcitinib to be recommended through managed access.</p> <p>Do you consider that the use of povorcitinib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?</p> <p>Yes. As stated above in the ‘timing issues’ section, moderate to severe HS carries a high psychosocial burden on patients, including depression and anxiety. People with HS often experience significant stigma because the condition causes painful, recurrent lesions in intimate body areas that may produce drainage, scarring and odour. This can lead to embarrassment, social isolation and psychological distress, with studies showing higher rates of depression and anxiety compared with the general population.⁶</p>	

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		<p>Several patient-reported outcome (PRO) instruments have been used in HS to measure aspects of the disease, including the Dermatology Life Quality Index (DLQI), Skin Pain Numeric Rating Scale (NRS) score, Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT F) score but these measures may not fully capture the emotional, social, and identity-related impacts of the disease.</p> <p>Matusiak 2020 Hidradenitis suppurativa and quality of life. Journal of Clinical Medicine.</p>	
Additional comments on the draft scope	BAD	<p>It should be noted that successfully preventing disease progression will have large economic benefits in the HS population which is nearly all of working age. Uncontrolled disease leads to high healthcare resource utilisation in the form of A&E attendances, need for surgery and prolonged wound healing times, and the burden of comorbid health problems such as depression, anxiety and cardiovascular disease. In Finland, HS was associated with a 15-year decrease in life expectancy, compared to 4 years for psoriasis (https://doi.org/10.1111/bjd.17578). The UK economic burden of HS was quantified as £3.8 billion per year by the Office of Health Economics (Theakston C, <i>et al.</i> 2023. The Burden of Hidradenitis Suppurativa on Patients, the NHS and Society: Estimates and Recommendations. OHE Contract Research Report, London: Office of Health Economics. https://www.ohe.org/publications/burden-hidradenitis-suppurativa-recommendations/). Additionally, HS is associated with a large burden of</p>	Thank you for your comments. The evidence for povorcitinib will be considered during the evaluation. No action is needed.

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		hospital attendances for young patients of working age and high NHS resource costs (https://doi.org/10.1111/bjd.14976).	

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

Novartis