National Institute for Health and Care Excellence

Health Technology Evaluation

Bimekizumab for treating moderate to severe hidradenitis suppurativa [ID6134]

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	A single technology appraisal is appropriate.	Comment noted. No action required.
	Novartis Pharmaceuticals UK Limited	Novartis agrees that the proposed evaluation is appropriate.	Comment noted. No action required.
	UCB Pharma Ltd. (company)	A Single Technology Appraisal is the most appropriate route.	Comment noted. No action required.
Wording	British Association of Dermatologists	The wording is appropriate.	Comment noted. No action required.

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	Novartis Pharmaceuticals UK Limited	Novartis considers the wording of the remit to be appropriate.	Comment noted. No action required.
	UCB Pharma Ltd. (company)	The draft remit is appropriate.	Comment noted. No action required.
Timing	British Association of Dermatologists	High urgency	Comment noted. We aim to publish final guidance for all new technologies within 90 days of receiving marketing authorisation.
	UCB Pharma Ltd. (company)	There are no timing issues to note at this time, if this changes, UCB will provide an update.	Comment noted. No action required.
Additional comments on the draft remit	British Association of Dermatologists	There is a high level of urgency because hidradenitis suppurativa (HS) is a relatively common condition for which there is currently only one licensed and NICE-approved therapy which quite often is insufficient. Access to infliximab is very limited, despite being recommended in BAD guidelines (https://onlinelibrary.wiley.com/doi/10.1111/bjd.17537), because it has not received NICE approval due to insufficient RCT evidence.	Comment noted. We aim to publish final guidance for all new technologies within 90 days of receiving marketing authorisation.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Novartis Pharmaceuticals UK Limited	Novartis agrees that the background information is appropriate.	Comment noted. No action required.
Population	British Association of Dermatologists	Yes [defined appropriately]	Comment noted. No action required.
	Novartis Pharmaceuticals UK Limited	Novartis considers the population stated in the draft scope to be appropriate.	Comment noted. No action required.
	AbbVie Ltd.	No comments	No action required.
Subgroups	British Association of Dermatologists	No, we do not currently have agreed sub-phenotypes of HS or specific sub-populations who should be considered separately.	Comment noted. No action required.
	Novartis Pharmaceuticals UK Limited	No comment.	No action required.
Comparators	British Association of Dermatologists	Yes, provided adalimumab also includes its biosimilars. It should be noted that 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.	The scope notes that the availability and cost of biosimilar and

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			generic products should be taken into account. Comment regarding best supportive care being difficult to define has been noted.
	Novartis Pharmaceuticals UK Limited	No comment.	No action required.
Outcomes	British Association of Dermatologists	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 *et al.* 2018 https://pubmed.ncbi.nlm.nih.gov/29654696/).	Comment noted. Specific measurement scales are not typically included in the scope. No action required.
	Novartis Pharmaceuticals UK Limited	Novartis agrees that the proposed outcomes are appropriate.	Comment noted. No action required.
Equality	British Association of Dermatologists	Probable higher incidence in people of Afro-Caribbean family background has been correctly identified. Please bear in mind that peak prevalence (2%) is in females of child-bearing age.	Comment noted. No action required.

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Other considerations	British Association of Dermatologists	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.	Comment noted. The background section has been edited to reflect this.
	British Association of Dermatologists	**What is the current treatment pathway for people with moderate to severe hidradenitis suppurativa?** The pathway follows the BAD guidelines 2018 (https://onlinelibrary.wiley.com/doi/10.1111/bjd.17537), with three main differences: (1) Dapsone is being used less and less because, while it has benefit in relatively mild disease, it is rarely sufficiently effective as monotherapy for moderate-to-severe disease. (2) Infliximab is not available in England, despite featuring in the guidelines. (3) Adalimumab primary or secondary failure is relatively common and co-treatments such as long-term antibiotics are being added to maintain disease control in the absence of other treatment options.	Comment noted. The background section has been updated to state that some people do not respond, or stop responding, to adalimumab. Additional information has also been added on infliximab.
		Where do you consider bimekizumab will fit into the existing care pathway for hidradenitis suppurativa? Immediately after adalimumab, in the context that adalimumab biosimilars have reduced the price considerably.	Comment noted. No action required.
		Are there different treatments for moderate or severe hidradenitis suppurativa? The treatments are those covered by the BAD guidelines (Ingram *et al.* 2018, 10.1111/bjd.17537). In the past, adalimumab has been used more for severe	Comment noted. No action required.

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		disease, however, it is increasingly used for moderate disease in order to prevent disease progression, including scarring.	
		Is infliximab considered to be established clinical practice in the NHS for treating hidradenitis suppurativa? Infliximab was established clinical practice for HS previously, but lack of access in England means it is rarely used now.	Comment noted. No action required.
		Should oral antibiotics, dapsone, retinoids, TNF-inhibitors (other than adalimumab) or surgery be included as comparators? No, oral therapies and surgery are used as concomitant treatments, rather than in place of biologic therapy. There are insufficent data for anti-TNF inhibitors for HS other than adalimumab.	Comment noted. No action required.
		Are biosimilars likely to be established clinical practice for the treatment of hidradenitis suppurativa? Yes – adalimumab.	Comment noted. No action required.
		Would bimekizumab be a candidate for managed access? Possibly, however, the phase III trial data presented at the AAD conference in March 2023 and due for imminent publication in a peer-reviewed journal should provide sufficient evidence. A British Association of Dermatologists-supported UK registry for HS, H-STRONG, will be operational in 2024, which should provide UK real world evidence for bimekizumab in HS.	Comment noted. No action required.

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		Do you consider bimekizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)? Bimekizumab will provide a step-change in HS management, as one of the first anti-IL17 therapies available for HS and a much needed alternative biologic for the quite high proportion of HS patients exhibiting adalimumab 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 (Kimball *et al.* 2016, https://pubmed.ncbi.nlm.nih.gov/27518661/). Prevention of scarring is very important and so options to allow treatment switching due to insufficient response to adalimumab are vital to prevent disease progression, which in turn causes greater impact on patients and the NHS. **Do you consider that the use of bimekizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** Patients report that pain is a key part of living with HS. While some of the functional impact of pain is included in QALY calculations, the burden of living with either chronic pain, or unpredictable episodic pain associated with flares, should not be underestimated. Pain scores of 10/10 (worst pain imaginable) are quite often reported in HS. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** Important to include pain numerical rating scale/visual analogue scale data.	Comment noted. The background section has been updated to state that some people do not respond, or stop responding, to adalimumab. Additional information has also been added regarding scarring. Comment noted. The background section has been updated to note that HS can be extremely painful. Comment noted. Pain is included as an outcome.

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	UCB Pharma Ltd. (company)	1. What is the current treatment pathway for people with moderate to severe hidradenitis suppurativa? Where do you consider bimekizumab will fit into the existing care pathway? If another IL-17 inhibitor was available, how would the treatments be sequenced? 2. Do you anticipate that bimekizumab will be used only where adalimumab is contraindicated or otherwise unsuitable, including those whose HS has not responded to prior adalimumab treatment? UCB anticipate that secukinumab and bimekizumab will be offered at the same place in the treatment pathway. 3. Are there different treatments for moderate vs. severe hidradenitis suppurativa? For patients with severe hidradenitis suppurativa surgical interventions are more frequently used. 4. Have all relevant comparators for bimekizumab in treating hidradenitis suppurativa been included in this scope? 5. Is infliximab considered to be established clinical practice in the NHS for treating hidradenitis suppurativa? 6. Should oral antibiotics, dapsone, retinoids, TNF-inhibitors (other than adalimumab) or surgery be included as comparators to bimekizumab? Or would they be used at a different point in the treatment pathway to bimekizumab?	Comment noted. No action required. Comment noted. No action required.

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		7. What does best supportive care for moderate to severe hidradenitis suppurativa consist of? The comparators in the scope are appropriate. As described in the NHS England Clinical Commissioning Policy the data on infliximab efficacy and safety are of insufficient quantity and quality to allow assessment of infliximab in HS. Oral antibiotics, dapsone, retinoids, and surgery are part of the standard of care in HS. Other elements of the standard of care in HS are pain management, lifestyle modification, and treatments for comorbidities of HS such as anxiety and depression. Biologic treatments may be given in addition to the standard of care, especially with regard to the treatment of infections and removal of damaged tissue. 8. Are biosimilars established clinical practice for the treatment of hidradenitis suppurativa? Adalimumab is licenced and recommended in HS, therefore biosimilar and branded adalimumab are expected to be used in the NHS. 9. Are there any subgroups of people in whom bimekizumab is expected to be more clinically effective and cost effective, or other groups that should be examined separately? UCB are unable to answer this question, at this time. 10. Would bimekizumab be a candidate for managed access? 11.	Comment noted. No action required. Comment noted. No action required. Comment noted. No action required. Comment noted. No action required.

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		Bimekizumab has a confidential simple discount patient access scheme. 12. Do you consider that the use of bimekizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? 13. Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. UCB are unable to answer this question at this time. Several disease specific quality of life measures exist or are under development in HS. There is also a generic skin-related quality of life instrument, the DLQI. Further analysis would be needed to assess whether EQ-5D sufficiently captures the effects on patient quality of life of HS, or whether EQ-5D adequately captures the benefits of biologic therapies to patients with HS.	Comment noted. No action required. Comment noted. No action required.
Additional comments on the draft scope	British Association of Dermatologists	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.	Comment noted. Healthcare resource use and the impact of HS on people's ability to live a normal life will be considered during the appraisal. No action required.

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

AbbVie Ltd.