NICE National Institute for Health and Care Excellence

Consultation on the appraisal consultation document – deadline for comments 5pm on 24th April **email:** TACommB@nice.org.uk

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. The Appraisal Committee is interested in receiving comments on the following: • has all of the relevant evidence been taken into account? • are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? • are the provisional recommendations sound and a suitable basis for guidance to the NHS? NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the preliminary recommendations may need changing in order to meet these aims. In particular, please tell us if the preliminary recommendations: • could have a different impact on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology; • could have any adverse impact on people with a particular disability or disabilities. Please provide any relevant information or data you have regarding such impacts and how they could be avoided or reduced**.**
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	**British Association of Dermatologists (the BAD)**
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	[**N/A**]
Name of commentator person completing form:	**Drs Pamela McHenry, Michael Ardern-Jones, Carsten Flohr, Richard Weller, Graham Johnston and Profs Michael J. Cork and Catherine Smith on behalf of the Therapy & Guidelines and A*STAR sub-committees of the British Association of Dermatologists**

Dupilumab for treating moderate to severe atopic dermatitis after topical treatments [ID1048]

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Comment number	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1	From a clinical perspective, following experience of limited use in trials and during the EAMS phase, the BAD would like to highlight the life-transforming nature of dupilumab treatment in many patients. People with severe atopic eczema are a high-need population who have few treatment options (most of which are unlicensed and have very little or no evidence base) [Roekevisch, J Allergy Clin Immunol 2014,133: 429-38]. As dermatologists, we are exposed to NICE-approved, high-cost drugs for dermatological disease and have gained experience of the appropriate ratio for cost effectiveness in clinical practice. We strongly believe that the benefit accrued by dupilumab to patients with (severe) atopic dermatitis should be supported by the NHS and disagree with the decision to reject funding for this treatment.
2	Based on expert opinion, the BAD considers that best supportive care is not well represented by the placebo arm of these trials. The reduction of topical corticosteroids usage amongst those on the dupilumab arm (despite failure to achieve 100% clearance) as shown in the CAFÉ trial, but continued use in the placebo arm, suggests that the observed positive effects of dupilumab vs. placebo would have been greater if topical corticosteroids usage had been continued. We predict that the placebo response would regress towards baseline if followed for a longer time period as patients gradually give up on the intensive topical therapy required to maintain the placebo response. This is supported by the NICE analysis which shows that *with* best supportive care, EASI50 & DLQI $\geq$ 4 responders drop off much more significantly in the placebo/best supportive care groups (25% loss) than in the dupilumab groups (4-5% loss) between 16 and 52 weeks across all studies. Loss of placebo effect should be incorporated into the model.
3	The health economic model needs to reflect the fact that patients with severe disease are likely to benefit more in terms of QALY change than those with moderate disease. Bearing in mind that disease severity data was captured for all patients, it would be relatively straightforward for Sanofi to provide a subgroup health economic analysis for the cohort of patients with severe disease.
4	Patients with severe disease are highly unlikely to remain on best supportive care as this is not tolerable for them (as described in the trial) as they require systemic therapy. Therefore, this group will generate increased costs from other areas not currently included in the model. These may include the cost of increased visits to GPs and dermatologists, admissions, complications from inappropriate use of prednisolone and toxicities from high dose systemic immunosuppression (for example nephrotoxicity with ciclosporin, skin cancer with azathioprine)
5	We suggest that 'severe' disease (as opposed to moderate) should be defined clinically by atopic dermatitis requiring systemic therapy because of its profound impact on patients' quality of life [Simpson, J Am Acad Dermatol 2017, 77: 623-33] For the purposes of the health economic evaluation, 'severe' atopic dermatitis corresponds to an EASI score of $\geq$ 21.1 [Leshem, Br J Dermatol 2015,172: 1353-7],

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	mirroring the severity inclusion criterion for the CAFÉ trial (EASI score ≥ 20 at screening and baseline).
5	
6	
7	
8	

Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 set of comments from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Please underline all confidential information, and separately highlight information that is submitted under 'commercial in confidence' in turquoise and all information submitted under 'academic in confidence' in yellow. If confidential information is submitted, please also send a 2nd version of your comment with that information replaced with the following text: 'academic / commercial in confidence information removed'. See the Guide to the processes of technology appraisal (section 3.1.23 to 3.1.29) for more information.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Do not use abbreviations
- Do not include attachments such as research articles, letters or leaflets. For copyright reasons, we will have to return comments forms that have attachments without reading them. You can resubmit your comments form without attachments, it must send it by the deadline.
- If you have received agreement from NICE to submit additional evidence with your comments on the appraisal consultation document, please submit these separately.

Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations 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 comments we received, and are not endorsed by NICE, its officers or advisory committees.