NICE National Institute for Health and Care Excellence

Lanadelumab for preventing recurrent attacks of hereditary angioedema [ID1268]

Consultation on the appraisal consultation document – deadline for comments 5pm on Friday 19 July 2019 **email:** NICE DOCS

	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):	**United Kingdom Primary Immunodeficiency Network (UKPIN)**
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	**No links to the tobacco industry**
Name of commentator person completing form:	**Patrick Yong**

Comment number	**Comments** Insert each comment in a new row.

Please return to: **NICE DOCS**

NICE National Institute for Health and Care Excellence

Lanadelumab for preventing recurrent attacks of hereditary angioedema [ID1268]

Consultation on the appraisal consultation document – deadline for comments 5pm on Friday 19 July 2019 **email:** NICE DOCS

	Do not paste other tables into this table, because your comments could get lost – type directly into this table.
Example 1	We are concerned that this recommendation may imply that ……..
1	We are concerned that this recommendation does not take into account the actual amount of Berinert and Cinryze used in clinical practice for prophylaxis. UKPIN has completed a snap survey of immunology centres to determine this. 82% (28 out of 34) of immunology centres responded in time, contributing data from 66 patients on prophylaxis with C1 inhibitor. Patients on Berinert (n=33) were using an average of 2781 units per week for prophylaxis and patients on Cinryze (n=31) were using an average of 2343 units per week for prophylaxis. Two patients on Ruconest were on 8400 units per week prophylaxis. The average usage per week for prophylaxis is higher than the licensed dose of Cinryze and the assumed fixed dose of 1000 units of Berinert twice per week. We would like to know what the cost-effectiveness data looks like with these figures. This data also indicates that the actual usage of Berinert for prophylaxis is higher than the fixed dose used in the model.
2	We are concerned the model does not seem to take into account the additional costs associated with treatment of breakthrough attacks for patients on prophylaxis (i.e. medication, additional hospital visits etc). We would expect there to be a greater reduction in breakthrough attacks in patients treated with lanadelumab rather than iv C1 inhibitor. The average number of breakthrough attacks in HAE patients in the UKPIN snap survey was 2.4 per month (data on breakthrough attacks available for 27 patients), which is a lot higher than the number of breakthrough attacks for patients in the HELP study. We would be like to see the additional costs associated with this included in the cost-effectiveness analysis.
3	We would also like to stress that lanadelumab is a genuinely innovative prophylactic treatment for patients with HAE, and has the potential to reduce both burden of treatment (significantly less injections) and burden of illness (less attacks compared to iv C1 inhibitor prophylaxis). The reduced burden of treatment and burden of illness means less days off work/school (reduced economic impact) and reduced anxiety for patients – these are factors which would not necessarily be accounted for in the model used.
4	
5	
6	

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

Please return to: **NICE DOCS**

Lanadelumab for preventing recurrent attacks of hereditary angioedema [ID1268]

Consultation on the appraisal consultation document – deadline for comments 5pm on Friday 19 July 2019 **email:** NICE DOCS

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.