NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Single Technology Appraisal

Omalizumab for previously treated chronic spontaneous urticaria

Consultee and commentator comment form

Please use this form for submitting your comments on the draft remit, draft scope and provisional matrix of consultees and commentators. It is important that you complete and return this form even if you have no comments otherwise we may chase you for a response.

Enter the name of your organisation here: British Association of Dermatologists

Comments on the draft remit and draft scope

The draft remit is the brief for a proposed appraisal. Appendix B contains the draft remit. The draft scope, developed from the draft remit outlines the question that the proposed appraisal would answer.

Please submit your comments on the draft remit and draft scope using the table below. **Please take note of any questions that have been highlighted in the draft scope itself** (usually found at the end of the document).

If you have been asked to comment on documents for more than one proposed appraisal, please use a separate comment form for each topic, even if the issues are similar.

If you do not have any comments to make on the draft remit and draft scope, please state this in the box below.

Comment 1: the draft remit

Section	*Notes*	Your comments
Appropriateness	*It is important that appropriate topics are referred to NICE to ensure that NICE guidance is relevant, timely and addresses priority issues, which will help improve the health of the population. Would it be appropriate to refer this topic to NICE for appraisal?*	
Wording	*Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider? If not, please suggest alternative wording.*	
Timing Issues	*What is the relative urgency of this proposed appraisal to the NHS?*	

Section	*Notes*	Your comments
Any additional comments on the draft remit		

Comment 2: the draft scope

Section	*Notes*	Your comments
Background information	*Consider the accuracy and completeness of this information.*	Most of the relevant information appears in the introduction as per the latest European guidelines on the management of urticaria. The only omission is that pulses of prednisolone can be used for exacerbations. Dapsone and the H2-receptor antagonists (e.g. ranitidine) no longer appear in the guidelines treatment algorithm, but are still useful in clinical practice.
The technology/ intervention	*Is the description of the technology or technologies accurate?*	
Population	*Is the population defined appropriately? Are there groups within this population that should be considered separately?*	
Comparators	*Is this (are these) the standard treatment(s) currently used in the NHS with which the technology should be compared? Can this (one of these) be described as 'best alternative care'?*	
Outcomes	*Will these outcome measures capture the most important health related benefits (and harms) of the technology?*	Outcomes can be measured by DLQI (Dermatology Life Quality Index) and UAS7 (Urticarial Activity Scores over 7 days assessing weals and itch). Frequency and duration of urticarial rash could be added to the outcome measures.
Economic analysis	*Comments on aspects such as the appropriate time horizon.*	
Equality	*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 proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:* • *could exclude from full consideration any people protected by the equality legislation who fall within the patient population for*	

Section	*Notes*	Your comments
	which [the treatment(s)] is/are/will be licensed; • *could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. 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 tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.*	
Other considerations	*Suggestions for additional issues to be covered by the proposed appraisal are welcome.*	
Innovation	*Do you consider the technology 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)?* *Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.*	
Questions for consultation	*Please answer any of the questions for consultation if not covered in the above sections. If appropriate, please include comments on the proposed process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).*	

Any additional comments on the draft scope

Omalizumab is recommended as treatment for resistant urticaria alongside ciclosporin or the leukotriene inhibitor, monteleukast. In practice, one would try second-line therapies as outlined in the introduction (including mycophenolate mofetil) before proceeding to omalizumab as is recommended for other conditions which require biologics in treatment resistance and patients with severe disease.

Omalizumab has been found to be helpful in all types of urticaria not just chronic spontaneous urticaria.

Phase 111 studies have been completed and address side effects, dosage and efficacy. Global, American, European and British guidelines exist.

The technology is innovative and this medication will contribute significantly to a better quality

Section	*Notes*	Your comments
of life and disease control in patients not responding to other treatments.		

Comment 3: provisional matrix of consultees and commentators

The provisional matrix of consultees and commentators (Appendix C) is a list of organisations that we have identified as being appropriate to participate in this proposed appraisal. If you have any comments on this list, please submit them in the box below.

As NICE is committed to promoting equality and eliminating unlawful discrimination Please let us know if we have missed any important organisations from the lists contained within the matrix, and which organisations we should include that have a particular focus on relevant equality issues.

If you do not have any comments to make on the provisional matrix of consultees and commentators, please cross this box: ☐

Comments on the provisional matrix of consultees and commentators
The British Society for Allergy and Clinical Immunology should be included in the stakeholder list.

Comment 4: regulatory issues

Section	*Notes*	Your comments
Remit	*Does the wording of the remit reflect the current or proposed marketing authorisation? If not, please suggest alternative wording.*	
Current or proposed marketing authorisation	*What are the current indications for the technology?*	
	What are the planned indications for the technology?	
	FOR EACH PLANNED INDICATION:	
	What is the target date (mm/yyyy) for regulatory submission?	
	Which regulatory process are you following?	
	What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable) and regulatory approval?	

Section	*Notes*	Your comments
	Please indicate whether the information you provide concerning the proposed marketing authorisation is in the public domain and if not when it can be released. All commercial in confidence information must be highlighted and underlined.	
Economic model software	*NICE accepts executable economic models using standard software, that is, Excel , DATA, R or WinBUGs. Please indicate which software will be used. If you plan to submit a model in a non-standard package, NICE, in association with the ERG, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the ERG with temporary licences for the non –standard software for the duration of the appraisal. NICE reserves the right to reject economic models in non-standard software*	

Please return this form, preferably by e-mail, to **scopingta@nice.org.uk** by **Monday 9 December 2013.**

Where email is not possible, please copy this completed form onto a CD-ROM and send to: Michelle Adhemar, Project Manager, NICE, 10 Spring Gardens, London, SW1A 2BU United Kingdom to arrive on or before the deadline. Further contact details are phone: 44 (0)20 7045 2239 fax: 44 (0)20 7061 9732