

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Multiple Technology Appraisal

#### Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people [ID854]

#### Consultee and commentator comment form

Please use this form for submitting your comments on the 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.

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

#### Comments on the remit and draft scope

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

Please submit your comments on the 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 appraisal, please use a separate comment form for each topic, even if the issues are similar.**

Please complete this form and upload it to NICE Docs by 24 March 2016. If you have any questions please contact the Project Manager – [Jeremy.Powell@nice.org.uk](mailto:Jeremy.Powell@nice.org.uk) / 020 7045 2248.

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

|  |
|--|
|  |
|--|

#### Comment 1: the remit

| Section         | Notes                                                                                                                                                                                                     | Your comments                                                                                                   |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| Appropriateness | <i>It is important that NICE guidance is relevant, timely and addresses priority issues, which will help improve the health of the population. Would this topic be appropriate for a NICE appraisal?</i>  | Yes. Presently there are no biological therapies with NICE approval for the treatment of psoriasis in children. |
| Wording         | <i>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.</i> | Yes.                                                                                                            |
| Timing Issues   | <i>What is the relative urgency of</i>                                                                                                                                                                    | Urgent; with the licensing of three biological                                                                  |

| Section                                                                                                                                                                   | Notes                             | Your comments                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-----------------------------------------------------------------------------|
|                                                                                                                                                                           | <i>this appraisal to the NHS?</i> | therapies for use under 16 years of age this has now become very important. |
| <p>Any additional comments on the remit</p> <p>None of the standard systemic therapies, used to treat psoriasis in children are licensed for use for this indication.</p> |                                   |                                                                             |

**Comment 2: the draft scope**

| Section                      | Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Your comments                                                                                                                                                                                                                                                                                             |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Background information       | <i>Consider the accuracy and completeness of this information.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | None.                                                                                                                                                                                                                                                                                                     |
| The technology/ intervention | <i>Is the description of the technology or technologies accurate?</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Yes. It is likely that data for secukinumab will be available in the next two years.                                                                                                                                                                                                                      |
| Population                   | <i>Is the population defined appropriately? Are there groups within this population that should be considered separately?</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Yes.                                                                                                                                                                                                                                                                                                      |
| Comparators                  | <i>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'?</i>                                                                                                                                                                                                                                                                                                                                                                                                                          | Yes, with the caveat that the standard systemic agents are not licensed for use in this group.                                                                                                                                                                                                            |
| Outcomes                     | <i>Will these outcome measures capture the most important health related benefits (and harms) of the technology?</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>In children, the cDLQI has become the gold standard for assessment of quality of life impact. A PGA or a PASI 90/ 75 or minimal or clear disease would be used for disease severity.</p> <p>The PASI was never validated in the paediatric population but has become the gold standard for adults.</p> |
| Economic analysis            | <i>Comments on aspects such as the appropriate time horizon.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Appropriate.                                                                                                                                                                                                                                                                                              |
| Equality                     | <p><i>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 remit and scope may need changing in order to meet these aims. In particular, please tell us if the remit and scope:</i></p> <ul style="list-style-type: none"> <li><i>could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;</i></li> </ul> | <p>Children with psoriasis may have inflammatory bowel disease as well as the JIA variant of psoriatic arthritis.</p> <p>Obviously children are more likely to prefer oral medication than an injection.</p>                                                                                              |

| Section                    | Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Your comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                            | <ul style="list-style-type: none"> <li>• 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;</li> <li>• 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.</li> </ul>                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Other considerations       | Suggestions for additional issues to be covered by the appraisal are welcome.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | None.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Innovation                 | <p><i>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)?</i></p> <p><i>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?</i></p> <p><i>Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.</i></p> | <p>This would be a step-change in paediatric care since there are no biological therapies currently licensed for use.</p> <p>There are now published trials for etanercept, ustekinumab and adalimumab.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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 process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).                                                                                                                                                                                                                                                                                                                                                                 | <p>Currently there is no formal treatment pathway for children as many of the therapeutic interventions are not licensed under 16 years of age. These children are treated, largely in line with pathways for adult disease as the draft scope indicates.</p> <p>There is limited off-license use of biological therapies in the NHS in young people with severe psoriasis who have failed standard systemic therapy.</p> <p>Due to the licensing restriction of the biological therapies, this was generally using etanercept as a first line biological agent. However, now adalimumab and ustekinumab are licensed this may change, especially since children would prefer fewer injections to gain disease control.</p> <p>It will be difficult to get good quality data to compare biological therapies as treatment modalities in this group. However, not all patients respond to the same therapeutic</p> |

| Section                                                                        | Notes | Your comments                                                                                                                                                                                                                                                                                                                                                                                                        |
|--------------------------------------------------------------------------------|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                |       | <p>intervention and it would be important not to restrict choice or the sequential use of these agents in cases where there was primary or secondary failure.</p> <p>The outcome measures should be for minimal or clear disease and health-related quality of life measures. The PASI 75 or 90 is also useful but not validated for use in children although the published RCTs have used this outcome measure.</p> |
| <p>Any additional comments on the draft scope<br/>None not already raised.</p> |       |                                                                                                                                                                                                                                                                                                                                                                                                                      |

**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 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 we are keen to know if we have missed any important organisations from the lists contained within the matrix and which organisations we should include who 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:

|                                                                          |
|--------------------------------------------------------------------------|
| <p>Comments on the provisional matrix of consultees and commentators</p> |
|--------------------------------------------------------------------------|

**Comment 4: regulatory issues (to be completed by the company that markets the technology)**

| Section                                     | Notes                                                                                                                                     | Your comments |
|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Remit                                       | <i>Does the wording of the remit reflect the current or proposed marketing authorisation? If not, please suggest alternative wording.</i> |               |
| Current or proposed marketing authorisation | <i>What are the current indications for the technology?</i>                                                                               |               |
|                                             | <i>What are the planned indications for the technology?</i>                                                                               |               |
|                                             | <i>FOR EACH PLANNED</i>                                                                                                                   |               |

| Section                 | Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Your comments |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
|                         | <i>INDICATION:</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |               |
|                         | <i>Which regulatory process are you following</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |               |
|                         | <i>? What is the target date (mm/yyyy) for regulatory submission?</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |               |
|                         | <i>What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable)</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                       |               |
|                         | <i>What is the anticipated date for regulatory approval?</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |               |
|                         | <i>What is the anticipated date for UK launch?</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |               |
|                         | <i>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.</i>                                                                                                                                                                                                                                                                                          |               |
| Economic model software | <i>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 AG, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the AG 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</i> |               |

Please complete this form and upload it to NICE Docs by 23 March 2016. If you have any questions please contact the Project Manager – [Jeremy.Powell@nice.org.uk](mailto:Jeremy.Powell@nice.org.uk) / 020 7045 2248.