Technology Appraisal Committee Meeting (Committee C)

Minutes: Confirmed

Date and Time: Wednesday 15 June 2015, 10:00 - 16:00

Venue: National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester
M1 4BT

Present:

1. Chair Professor Andrew Stevens Present for all notes
2. Dr Ian Bernstein Present for all notes
3. David Chandler Present for all notes
4. Gail Coster Present for all notes
5. Professor Rachel Elliott Present for notes 10 to 18
6. Dr Nigel Langford Present for all notes
7. Professor Andrea Manca Present for all notes
8. Dr Iain Miller Present for all notes
9. Dr Paul Miller Present for all notes
10. Vice Chair Professor Eugene Milne Present for all notes
11. Professor Stephen O’Brien Present for all notes
12. Dr Anna O’Neill Present for all notes
13. Mr Malcolm Oswald Present for notes 05 to 09
14. Professor Andrew Renehan Present for all notes
15. Dr Peter Selby Present for all notes
16. Prof Matt Stevenson Present for notes 10 to 18
17. Dr Judith Wardle Present for all notes

In attendance:

Meindert Boysen Programme Director, National Institute for Health and Care Excellence Present for all notes

Dr Frances Sutcliffe Associate Director, National Institute for Health and Care Excellence Present for all notes

Stephanie Yates Project Manager, National Institute for Health and Care Excellence Present for all notes

Joanne Ekeledo Administrator, National Institute for Health and Care Excellence Present for all notes
<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Present for</th>
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<tbody>
<tr>
<td>Hamish Lunagaria</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>05 to 09</td>
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<tr>
<td>Joanne Holden</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>05 to 09 and for notes 15 to 18</td>
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<tr>
<td>Helen Tucker</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>10 to 14</td>
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<tr>
<td>Nicola Hay</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>10 to 14</td>
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<td>Boglarka Mikudina</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>15 to 18</td>
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<td>Professor Matt Stevenson</td>
<td>ERG representatives</td>
<td>05 to 09</td>
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<td>Dr Inigo Bermejo</td>
<td>ERG representatives</td>
<td>05 to 09</td>
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<td>Dr Rachel Archer</td>
<td>ERG representatives</td>
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<td>Rob Riemsma</td>
<td>ERG representatives</td>
<td>10 to 13</td>
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<td>Maiwenn Al</td>
<td>ERG representatives</td>
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<td>Annemieke van Dongen-Leunis</td>
<td>ERG representatives</td>
<td>10 to 13</td>
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<td>Angela Stainthorpe</td>
<td>ERG representatives</td>
<td>15 to 18</td>
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Notes

Welcome

1. The Chair welcomed all members of the Committee and other attendees present to the meeting. The Chair reviewed the agenda and timescales for the meeting, which included the appraisals of certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF inhibitor, pegaspargase for treating acute lymphoblastic leukaemia and nivolumab for previously treated locally advanced or metastatic non-squamous non-small-cell lung cancer

2. Apologies were received from Professor Kathryn Abel, Dr Paul Tappenden and Dr Robert Walton

Any other Business

3. None

Appraisal of certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF inhibitor
Part 1 – Open session

4. The Chair welcomed the invited experts: Dr Ben Parker and Mrs Alisa Bosworth to the meeting and they introduced themselves to the Committee.

5. The Chair welcomed company representatives from UCB Pharma to the meeting.

6. The Chair asked all Committee members to declare any relevant interests

6.1. Dr Ian Bernstein, David Chandler, Gail Coster, Dr Nigel Langford Professor Andrea Manca, Dr Iain Miller, Dr Paul Miller, Professor Eugene Milne, Professor Stephen O’Brien, Dr Judith Wardle, Mr Malcolm Oswald, Professor Andrew Renehan, Dr Peter Selby and Dr Anna O’Neill all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF inhibitor.

6.2. Professor Stephen O’Brien declared a non-personal specific financial interest. Over the past 12 months he has received support from Bristol-Myers Squibb (EHA 2015 and ASH 2015). The support that was required was for ‘booking and payment of reasonable accommodation, meals and travel to attend meetings and conferences’. Over the last 12 months my University and/or NHS Trust has received research funding for clinical trial work from the following companies: Pfizer and Bristol-Myers Squibb.

9.2.1 It was agreed that this declaration would not prevent Professor Stephen O’Brien from participating in this section of the meeting.

6.3. Professor Matt Stevenson is conflicted and did not attend the meeting as a committee member. He represented the ERG at the meeting.

6.4. Professor Rachel Elliott is conflicted and did not attend the meeting. She declared a personal financial interest.

7. The Chair asked all NICE Staff to declare any relevant interests.

7.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF inhibitor.

8. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

8.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF inhibitor.
9. The Chair introduced the lead team, Dr Anna O'Neill, Dr Paul Miller and Mr David Chandler who gave presentations on the clinical effectiveness and cost effectiveness of certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF inhibitor.

10. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

11. The Chair explained that “representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest” (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)“ and all public attendees left the meeting.

12. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

13. Discussion on confidential information continued. This information was supplied by the ERG.

14. The Committee continued to discuss the clinical and cost effectiveness of Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF inhibitor.

15. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of pegasparagase for treating acute lymphoblastic leukaemia

Part 1 – Open session

16. The Vice Chair welcomed the invited experts: Dr Clare Rowntree and Zack Pemberton-Whiteley to the meeting and they introduced themselves to the Committee.

17. The Vice Chair welcomed company representatives from Baxalta to the meeting.

18. The Vice Chair asked all Committee members to declare any relevant interests

18.1. Dr Ian Bernstein, David Chandler, Gail Coster, Professor Rachel Elliott, Dr Nigel Langford, Professor Andrea Manca, Dr Iain Miller, Dr Paul Miller, Professor Andrew Stevens, Professor Stephen O'Brien, Dr Anna O'Neill, Professor Andrew Renehan, Dr Peter Selby, Prof Matt Stevenson and Dr Judith Wardle all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of pegasparagase for treating acute lymphoblastic leukaemia.
19. The Vice Chair asked all NICE Staff to declare any relevant interests.

19.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of pegaspargase for treating acute lymphoblastic leukaemia.

20. The Vice Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

20.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of pegaspargase for treating acute lymphoblastic leukaemia.

21. The Vice Chair introduced the lead team, Mrs Gail Coster, Professor Rachel Elliott and Dr Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of pegaspargase for treating acute lymphoblastic leukaemia.

22. The Vice Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

23. The Vice Chair explained that “representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest” (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)” and all public attendees left the meeting.

24. The Vice Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

**Part 2 – Closed session**

25. The Committee continued to discuss the clinical and cost effectiveness of pegaspargase for treating acute lymphoblastic leukaemia.

26. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

**Appraisal of nivolumab for previously treated locally advanced or metastatic non-squamous non-small-cell lung cancer**

**Part 1 – Open session**

27. The Chair welcomed company representatives from Bristol-Myers Squibb Pharmaceuticals to the meeting.

28. The Chair asked all Committee members to declare any relevant interests
28.1. Dr Ian Bernstein, David Chandler, Gail Coster, Professor Rachel Elliott, Dr Nigel Langford, Professor Andrea Manca, Dr Iain Miller, Dr Paul Miller, Professor Eugene Milne, Professor Stephen O’Brien, Dr Anna O’Neill, Professor Andrew Renehan, Dr Peter Selby, Prof Matt Stevenson and Dr Judith Wardle all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of nivolumab for previously treated locally advanced or metastatic non-squamous non-small-cell lung.

28.2. Professor Stephen O’Brien declared a non-personal specific financial interest. Over the last 12 months I have received support from Bristol-Myers Squibb (EHA 2015 and ASH 2015). The support that was required was for ‘booking and payment of reasonable accommodation, meals and travel to attend meetings and conferences’ (NICE COI guidance). Over the last 12 months his University and/or NHS Trust has received research funding for clinical trial work from the following companies: Pfizer, Novartis and Bristol-Myers Squibb. He’s a member of the NCRI Clinical Studies Group (CSG), which oversees a portfolio of leukaemia trials in the UK. He has no current involvement with CLL trials – his involvement is in CML. Non-reimbursed position.

28.2.1 It was agreed that this declaration would not prevent Professor Stephen O’Brien from participating in this section of the meeting.

29. The Chair asked all NICE Staff to declare any relevant interests.

29.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of nivolumab for previously treated locally advanced or metastatic non-squamous non-small-cell lung cancer.

30. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

30.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of nivolumab for previously treated locally advanced or metastatic non-squamous non-small-cell lung cancer.

31. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

32. The Chair explained that “representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest” (Section 1(2) Public Bodies (Admission to
Meetings) Act 1960)" and all public attendees left the meeting.

33. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

34. Discussion on confidential information continued. This information was supplied by the company and ERG.

35. The Committee continued to discuss the clinical and cost effectiveness of nivolumab for previously treated locally advanced or metastatic non-squamous non-small-cell lung cancer.

36. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Date, time and venue of the next meeting

37. **Wednesday 13 July 2016 from 10:00 to 17:00** at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.