

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

Hamish Lunagaria	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 05 to 09
Joanne Holden	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 05 to 09 and for notes 15 to 18
Helen Tucker	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 10 to 14
Nicola Hay	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 10 to 14
Boglarka Mikudina	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 15 to 18
Non-public observers:		
Professor Matt Stevenson	ERG representatives	Present for notes 05 to 09
Dr Inigo Bermejo	ERG representatives	Present for notes 05 to 09
Dr Rachel Archer	ERG representatives	Present for notes 05 to 09
Rob Riemsma	ERG representatives	Present for notes 10 to 13
Maiwenn Al	ERG representatives	Present for notes 10 to 13
Annemieke van Dongen-Leunis	ERG representatives	Present for notes 10 to 13
Angela Stainthorpe	ERG representatives	Present for notes 15 to 18

Juliet Hockenull	ERG representatives	Present for notes 15 to 18
Marty Richardson	ERG representatives	Present for notes 15 to 18
Dr Ben Parker	Clinical Expert	Present for notes 05 to 08
Mrs Alisa Bosworth	Patient Expert	Present for notes 05 to 08
Dr Clare Rowntree	Clinical Expert	Present for notes 05 to 08 & 10 to 13
Zack Pemberton-Whiteley	Patient Expert	Present for notes 05 to 08 & 10 to 13
Jasdeep Hayre	NICE observer	Present for notes 10 to 14
Kate Moring	NICE observer	Present for all notes

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 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'. 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 pegaspargase 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 pegaspargase 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.