

Technology Appraisal Committee Meeting (Committee C)

Minutes: Confirmed

Date and Time: Wednesday 9 March 216, 10:00 – 17:00

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

Present:	1. Chair Professor Andrew Stevens 2. Dr Ian Bernstein 3. David Chandler 4. Gail Coster 5. Professor Peter Crome 6. Professor Rachel Elliott 7. Dr Nigel Langford 8. Dr Iain Miller 9. Dr Paul Miller 10. Professor Andrea Manca 11. Professor Andrew Renehan 12. Dr Claire Rothery 13. Prof Matt Stevenson 14. Dr Paul Tappenden 15. Professor Robert Walton 16. Dr Judith Wardle	Present for all notes Present for notes 01 to 08 and 13 to 16 Present for all notes 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

Stuart Wood	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 01 to 08
Nicola Hay	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 01 to 16
Zoe Garrett	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 01 to 08
Ahmed Elsada	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 09 to 16
Jasdeep Hayre	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 09 to 16
Joanne Holden	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 09 to 16
Ruben Mujica Mota	ERG representative	Present for notes 04 to 07
Tristan Snowsill	ERG representative	Present for notes 04 to 07
Irina Tikhonova	ERG representative	Present for notes 04 to 07
Jo Varley-Campbell	ERG representative	Present for notes 04 to 07
Paul Tappenden	ERG representative	Present for notes 09 to 11
Graham Scotland	ERG representative	Present for notes 13 to 15
Professor Antony Weirzbicki	Clinical Expert	Present for notes 09 to 11 and 13 to 15
Mrs Karen Hasid	Patient Expert	Present for notes 13 to 15
Mr Simon Williams	Clinical Expert	Present for notes 13 to 15
Dr Ebernard Blind	Observer	Present for notes 09 to 16
Kate Moring	Observer	Present for notes 04 to 12
Debbie Morrison	Observer	Present for notes 13 to 16

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 Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts, Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia and Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia
2. Apologies were received from Dr Anna O'Neill, Professor Kathryn Abel, Dr Peter Selby and Professor Stephen O'Brien

Any other Business

3. None

Appraisal of Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts

Part 1 – Open session

4. The Chair welcomed company representatives from Celgene to the meeting.
5. The Chair asked all Committee members to declare any relevant interests
 - 5.1. Dr Ian Bernstein, David Chandler, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Nigel Langford, Dr Iain Miller, Dr Paul Miller, Professor Andrea Manca, Professor Andrew Renahan, Dr Claire Rothery, Prof Matt Stevenson, Dr Paul Tappenden, Dr Judith Wardle, Professor Robert Walton 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 Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts.
6. The Chair asked all NICE Staff to declare any relevant interests.
 - 6.1. 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 Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts.
7. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their 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 Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts.

8. The Chair introduced the lead team, Professor Peter Crome, Dr Claire Rothery and Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts.
9. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
10. 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.
11. 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

12. The Committee continued to discuss the clinical and cost effectiveness of Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts.
13. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia

Part 1 – Open session

14. The Chair welcomed the invited experts: Professor Anthony Wierzbicki to the meeting and they introduced themselves to the Committee.
15. The Chair welcomed company representatives from Amgen to the meeting.
16. The Chair asked all Committee members to declare any relevant interests
 - 16.1. 5.1. Dr Ian Bernstein, David Chandler, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Nigel Langford, Dr Iain Miller, Dr Paul Miller, Professor Andrea Manca, Professor Andrew Renahan, Dr Claire Rothery, Prof Matt Stevenson, Dr Judith Wardle, Professor Robert Walton 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 Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia.

- 16.2. Paul Tappenden representing the ERG for this appraisal
17. The Chair asked all NICE Staff to declare any relevant interests.
 - 17.1. 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 Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia.
18. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
 - 18.1. 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 Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia.

The Chair introduced the key themes arising from the consultation responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.

19. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
20. 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.
21. 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

22. The Committee continued to discuss the clinical and cost effectiveness of Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia
23. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia

Part 1 – Open session

24. The Chair welcomed the invited experts: Professor Anthony Wierzbicki, Karen Hasid and Simon Williams to the meeting and they introduced themselves to the Committee.
25. The Chair welcomed company representatives from Sanofi to the meeting.

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

26.1. 5.1. Dr Ian Bernstein, David Chandler, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Nigel Langford, Dr Iain Miller, Dr Paul Miller, Professor Andrea Manca, Professor Andrew Renahan, Dr Claire Rothery, Prof Matt Stevenson, Dr Paul Tappenden, Dr Judith Wardle, Professor Robert Walton 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 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia.

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

27.1. 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 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia.

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

28.1. 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 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia.

The Chair introduced the key themes arising from the consultation responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.

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

30. 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.

31. 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

32. The Committee continued to discuss the clinical and cost effectiveness of Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia

33. 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

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