Technology Appraisal Committee Meeting Committee C

Minutes: Confirmed

Date and Time: Wednesday 18 November 2015, 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	Present for all notes
	2. David Chandler	Present for all notes
	3. Gail Coster	Present for all notes
	4. Professor Peter Crome	Present for all notes
	5. Dr Nigel Langford	Present for all notes
	6. Dr Iain Miller	Present for all notes
	7. Professor Eugene Milne	Present for all notes
	8. Professor Andrea Manca	Present for all notes
	9. Dr Patrick McKiernan	Present for all notes
	10. Dr Anna O'Neill	Present for all notes
	11. Dr Claire Rothery	Present for all notes
	12. Dr Peter Selby	Present for all notes
	13. Prof Matt Stevenson	Present for all notes
	14. Professor Robert Walton	Present for all notes
	15. 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
Lori Farrar	Project Manager, 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
Ian Watson	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
Chris Chesters	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
Jasdeep Hayre	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 15 to 19
Linda Landells	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 15 to 19

Non-public observers:

Adrian Bagust	ERG Representative	Present for notes 05 to 08
Nigel Fleeman	ERG Representative	Present for notes 05 to 08
Mariana Bacelar	ERG Representative	Present for notes 10 to 13
Andrea Berardi	ERG Representative	Present for notes 10 to 13
Steve Edwards	ERG Representative	Present for notes 10 to 13
Graham Scotland	ERG Representative	Present for notes 15 to 18
Mehdi Javanbakht	ERG Representative	Present for notes 15 to 18
Dr Lisa Anderson	Clinical Expert	Present for notes 15 to 18
Dr Simon Williams	Clinical Expert	Present for notes 15 to 18

Nick Hartshorne-Evans	Patient Expert	Present for notes 15 to 18
Emma Taylor	Patient Expert	Present for notes 15 to 18
Dr Matthew Hatton	Clinical Expert	Present for notes 05 to 08
Dr Sanjay Popat	Clinical Expert	Present for notes 05 to 08
Carole Davies	Patient Expert	Present for notes 05 to 08
Anna Brett	NICE Observer	Present for all notes
Boglarka Mikundina	NICE Observer	Present for notes 05 to 09
Ciara Donnelly	NICE Observer	Present for notes 15 to 18
Katie Wyart	NICE Observer	Present for all notes
Sophie Laurenson	NICE Observer	Present for notes 10 to 14

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 Nivolumab for treating metastatic, squamous, non-small-cell lung cancer after chemotherapy, Sacubitril valsartan for treating heart failure with systolic dysfunction and Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia (review of TA132

2. Apologies were received from Dr Claire Rothery, Dr David Black, Professor Kathryn Abel, Paul Miller, Paul Tappenden and Professor Rachel Elliott

Any other Business

3. None

Appraisal of Nivolumab for treating metastatic, squamous, non-small-cell lung cancer after chemotherapy

Part 1 – Open session

4. The Chair welcomed the invited experts: Carole Davies, Dr Matthew Hatton and Dr Sanjay Popat to the meeting and they introduced themselves to the Committee.

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

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

6.1. David Chandler, Gail Coster, Professor Peter Crome, Dr Nigel Langford, Dr Iain Miller, Professor Eugene Milne, Professor Andrea Manca, Dr Patrick McKiernan, Dr Anna O'Neill, Dr Claire Rothery, Dr Peter Selby, 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 Nivolumab for treating metastatic, squamous, non-small-cell lung cancer after chemotherapy

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 Nivolumab for treating metastatic, squamous, non-small-cell lung cancer after chemotherapy

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 Nivolumab for treating metastatic, squamous, non-small-cell lung cancer after chemotherapy

9. The Chair introduced the lead team, Dr Peter Selby, Dr Iain Miller and Dr Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of Nivolumab for treating metastatic, squamous, non-small-cell lung cancer after chemotherapy.

10. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Nivolumab for treating metastatic, squamous, non-small-cell lung cancer after chemotherapy on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:

10.1. The current management of squamous non-small-cell lung cancer in the NHS and the appropriate comparators for nivolumab in this population.
10.2. The clinical-effectiveness evidence presented by the company, including the CheckMate-017 trial.
10.3. The cost-effectiveness evidence, the results from the company's economic analysis and the critique and exploratory analyses from the Evidence Review Group.
10.4. The innovative nature of nivolumab and whether nivolumab met the criteria to be considered a life-extending, end-of-life treatment.

10.5. Whether nivolumab could be considered a cost-effective use of NHS resources.

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

12. 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.

13. 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

14. Discussion on confidential information continued. This information was supplied by the company.

15. The Committee continued to discuss the clinical and cost effectiveness of Nivolumab for treating metastatic, squamous, non-small-cell lung cancer after chemotherapy

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

Appraisal of Sacubitril valsartan for treating heart failure with systolic dysfunction

Part 1 – Open session

17. The Chair welcomed the invited experts: Dr Lisa Anderson, Nick Hartshorne – Evans, Dr Simon Williams and Emma Taylor to the meeting and they introduced themselves to the Committee.

18. The Chair welcomed company representatives from Novartis Pharmaceuticals to the meeting.

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

19.1. David Chandler, Gail Coster, Professor Peter Crome, Dr Nigel Langford, Dr Iain Miller, Professor Eugene Milne, Professor Andrea Manca, Dr Patrick McKiernan, Dr Anna O’Neill, Dr Claire Rothery, Dr Peter Selby, 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 Sacubitril valsartan for treating heart failure with systolic dysfunction.

20. The Chair asked all NICE Staff to declare any 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 Sacubitril valsartan for treating heart failure with systolic dysfunction.

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

21.1. 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 Sacubitril valsartan for treating heart failure with systolic dysfunction.

21.2. Dr Lisa Anderson declared a personal non- specific financial interest as she had run funded trails by Novartis, she also declared another non-personal non-specific financial interest she attended an advisory committee meeting for Novartis in November 2014

21.2.1. It was agreed that this declaration would not prevent Dr Lisa Anderson from participating in this section of the meeting

21.3. Dr Simon Williams declared a personal non- specific financial interest as he had run funded trails by Novartis and had done honorary advisory work again for Novartis.

21.3.1. It was agreed that this declaration would not prevent Dr Simon Williams from participating in this section of the meeting

21.4. Nick Hartshorne Evans declared a non-personal non-specific financial interest. The Pumping Marvellous Foundation has received funding from Novartis.

21.4.1. It was agreed that this declaration would not prevent Nick Hartshorne Evans from participating in this section of the meeting

22. The Chair introduced the lead team, Dr Nigel Langford, Dr Patrick McKiernan and David Chandler who gave presentations on the clinical effectiveness and cost effectiveness of Sacubitril valsartan for treating heart failure with systolic dysfunction.

23. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Sacubitril valsartan for treating heart failure with systolic dysfunction on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:

23.1. The treatment pathway for people with chronic heart failure and the position in the pathway for sacubitril valsartan.

23.2. The clinical effectiveness evidence from PARADIGM-HF comparing sacubitril valsartan with enalapril including the generalisability of the PARADIGM-HF trial results.

23.3. The company's network meta-analysis to estimate the relative treatment effect for sacubitril valsartan compared with ARBs

23.4. The cost-effectiveness evidence, the results from the company's economic analysis and the critique and exploratory analyses from the Evidence Review Group.

23.5. The innovative nature of sacubitril valsartan and whether sacubitril valsartan was a cost-effective use of NHS resources.

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

25. 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.

26. 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

27. Discussion on confidential information continued. This information was supplied by the company.

28. The Committee continued to discuss the clinical and cost effectiveness of Sacubitril valsartan for treating heart failure with systolic dysfunction.

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

Appraisal of Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia (review of TA132)

Part 1 – Open session

30. The Chair welcomed company representatives from Merck Sharp & Dohme to the meeting.

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

31.1. David Chandler, Gail Coster, Professor Peter Crome, Dr Nigel Langford, Dr Iain Miller, Professor Eugene Milne, Professor Andrea Manca, Dr Patrick McKiernan, Dr Anna O'Neill, Dr Claire Rothery, Dr Peter Selby, 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 Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia (review of TA132)

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

32.1. 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 Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia (review of TA132)

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

33.1. 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 Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia (review of TA132)

34. 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.

35. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia (review of TA132) on the basis of the evidence before them. The discussions included:

35.1. The relevance of the clinical trial IMPROVE-IT

35.2. The appropriateness of the company's approach to the economic modelling

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

37. 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.

38. 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

39. The Committee continued to discuss the clinical and cost effectiveness of Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia (review of TA132).

40. 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

41. Wednesday 13 January 2016, 1000 until 1700 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.