

Technology Appraisal Committee Meeting Committee C

Minutes: Confirmed

Date and Time: **Tuesday 24 March 2015, 10:00 to 14.00**

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

Present:	1. Chair Andrew Stevens 2. Gail Coster 3. Professor Peter Crome 4. Professor Rachel Elliott 5. Dr Alan Haycox 6. Dr Nigel Langford 7. Professor Andrea Manca 8. Dr Patrick McKiernan 9. Dr Iain Miller 10. Professor Eugene Milne 11. Professor Stephen O'Brien 12. Dr Anna O'Neill 13. Dr John Radford 14. Dr Peter Selby 15. Prof Matt Stevenson 16. Dr Paul Tappenden 17. Dr Judith Wardle	Present for all notes Present for notes 10 to 14 Present for all notes
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In attendance:

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
Joanne Ekeledo	Administrator, National Institute for Health and Care Excellence	Present for all notes
Dr Linda Landells	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 02 to 09

Fay McCracken	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 02 to 09
Steve Edwards	ERG Representative, BMJ	Present for notes 02 to 08
Gemma Marceniuk	ERG Representative, BMJ	Present for notes 02 to 08
Ewen Cummings	ERG Representative, Aberdeen HTA	Present for notes 10 to 13
Dr Miriam Brazelli	ERG Representative, Aberdeen HTA	Present for notes 10 to 13
Maria Dawson	Patient Expert	Present for notes 02 to 08
Gary Forrest	Patient Expert	Present for notes 02 to 08
Dr Ian Pearce	Clinical Expert	Present for notes 02 to 08
Dr Sobha Siva Prasad	Clinical Expert	Present for notes 02 to 08

Non-public observers:

Danielle Conroy	TA Administrator Committee D, National Institute for Health and Clinical Excellence	Present for notes all notes
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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 Dexamethasone intravitreal implant for treating diabetic macular oedema.
2. The Chair informed the Committee of the non-public observers at this meeting: Danielle Conroy.
3. Apologies were received from Dr Claire McKenna, Dr David Black, David Chandler, Professor Kathryn Abel, Dr Paul Miller, Robert Walton, Dr Suzanne Martin and Prof Wasim Hanif.

Any other Business

4. None

Appraisal of Dexamethasone intravitreal implant for treating diabetic macular oedema

Part 1 – Open session

5. The Chair welcomed the invited experts: Maria Dawson, Gary Forrest, Dr Ian Pearce and Dr Sobha Sivaprasad to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Allergan Ltd UK to the meeting.
7. The Chair asked all Committee members to declare any relevant interests

Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Alan Haycox, Dr Nigel Langford, Professor Andrea Manca, Dr Patrick McKiernan, Dr Iain Miller, Professor Eugene Milne, Professor Stephen O'Brien, Dr Judith Wardle, Dr John Radford, Dr Peter Selby, Prof Matt Stevenson, Dr Anna O'Neill all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Dexamethasone intravitreal implant for treating diabetic macular oedema.

- 7.1. Paul Tappenden declared a family specific financial interest as his partner works as a statistician for Bresmed and has undertaken a network meta-analysis of options for DMO on behalf of Allergan. He has not received any money from the manufacturer listed in the matrix and is not aware of the methods or results of the NMA
It was agreed that this declaration would prevent Paul Tappenden from participating in this section of the meeting.
8. The Chair asked all NICE Staff to declare any relevant interests.

8.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Dexamethasone intravitreal implant for treating diabetic macular oedema.

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

9.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Dexamethasone intravitreal implant for treating diabetic macular oedema.

9.2. Dr Sobha Sivaprasad declared a personal non specific pecuniary interest as she has had research grants, travel and speaker fees from both Allergan and Bayer.

9.2.1. It was agreed that this declaration would not prevent Dr Sobha Sivaprasad from participating in this section of the meeting

9.3. Dr Ian Pearce declared a personal non specific pecuniary interest as he has had consultancy fees from both Allergan and Bayer.

9.3.1. It was agreed that this declaration would not prevent Dr Ian Pearce from participating in this section of the meeting

10. 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.

11. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Dexamethasone intravitreal implant for treating diabetic macular oedema on the basis of the evidence before them. The discussions included:

11.1. Whether it was persuaded by the company's new evidence evaluating dexamethasone intravitreal implant compared with watch-and-wait in patients with a natural lens who either do not respond to, or are not suitable for, non-corticosteroid therapies.

11.1.1. The new evidence used head-to-head MEAD data and incorporated ERG corrections.

11.1.2. Other changes to the company's economic model included amendments to residential care costs, alternative transition matrices, alternative utility values and the introduction of a clinical continuation rule.

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

13. 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.

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

Part 2 – Closed session

15. Discussion on confidential information continued. This information was supplied by the company.
16. The Committee continued to discuss the clinical and cost effectiveness of Dexamethasone for treating diabetic macular oedema..
17. The Committee instructed the technical team to prepare the Final Appraisal Determination in line with their decisions.

Appraisal of Aflibercept for treating diabetic macular oedema

Part 1 – Open session

18. The Chair welcomed company representatives from Bayer plc to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
 - 19.1. Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Alan Haycox, Dr Nigel Langford, Professor Andrea Manca, Dr Patrick McKiernan, Dr Iain Miller, Professor Eugene Milne, Professor Stephen O'Brien, Dr Judith Wardle, Dr John Radford, Dr Peter Selby, Prof Matt Stevenson, Dr Anna O'Neill and Paul Tappenden all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Aflibercept for treating diabetic macular oedema.
20. The Chair asked all NICE Staff to declare any relevant interests.
 - 20.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Aflibercept for treating diabetic macular oedema.
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 pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Aflibercept for treating diabetic macular oedema.

22. 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.
23. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Aflibercept for treating diabetic macular oedema 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. Whether the Committee were persuaded by the Company's additional evidence and analysis for the comparison of aflibercept with laser treatment in the whole population.
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, company representatives and academic group 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 aflibercept for diabetic macular oedema .
29. 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

30. Tuesday, 21 April 2015, 10:00 – 17:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.