Technology Appraisal Committee Meeting (Committee C)

Minutes: Confirmed

Date and Time: Wednesday, 21 March 2018, 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 Stephen O'Brien Present for all notes

Mr Kamal Balakrishnan
Dr Alex Cale
Present for all notes
Present for all notes

4. Mr Michael Chambers Present for notes 1-16 & 29-39

5. Mr David Chandler Present for notes 16-39 6. Ms Gail Coster Present for all notes 7. Dr Prithwirai Das Present for all notes Present for all notes 8. Dr Natalie Hallas 9. Mr John Hampson Present for all notes 10. Dr Nigel Langford Present for all notes 11. Dr Rubin Minhas Present for all notes 12. Dr Richard Nicholas Present for all notes 13. Prof Andrew Renehan Present for all notes 14. Dr Peter Selby Present for all notes 15. Dr Paul Tappenden Present for all notes 16. Dr Judith Wardle Present for all notes

In attendance:

Helen Knight Associate Director, National Present for all notes

Institute for Health and

Care Excellence

Frances Sutcliffe Associate Director, National Present for all notes

Institute for Health and

Care Excellence

Linda Landells Associate Director, National Present for notes 17-25

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Stephanie Callaghan Project Manager, National Present for all notes

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Care Excellence

Tanith Musson Administrator, National Present for all notes

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Care Excellence

Kirsty Pitt Technical Analyst, National Present for notes 1-16 & 29-39

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Alex Filby Technical Adviser, National Present for notes 1-16

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Victoria Kelly Technical Analyst, National Present for notes 17-28

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Nicola Hay Technical Adviser, National Present for notes 17-28

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Care Excellence

Non-public attendees:

Notes

Welcome

 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 arsenic trioxide for treating acute promyelocytic leukaemia [ID446], brentuximab vedotin for treating CD30-positive Hodgkin's lymphoma (CDF Review of TA446) [ID1366] and midostaurin for untreated acute myeloid leukaemia [ID894]

- 2. The Chair welcomed Dr Alex Cale and Dr Rubin Minhas to their first meeting as a member of the Appraisal Committee
- 3. The Chair informed the Committee of the non-public observers at this meeting: Nicola Ace, Stephen Benson, Henry Edwards, Adeolu Grillo, Leslie Hayes, Emma Kent, Sarah Lawton, Louise Miller, Tosin Oladapo, Laura Worthington
- 4. Apologies were received from Professor Andrea Manca, Professor Matt Stevenson, Dr Derek Ward and Professor Robert Walton

Appraisal of arsenic trioxide for treating acute promyelocytic leukaemia [ID446]

Part 1 - Open session

- 5. The Chair welcomed the invited experts: Bram Ramaekers, Rob Riemsma, Nigel Russell to the meeting and they introduced themselves to the Committee.
- 6. The Chair welcomed company representatives from Teva to the meeting.
- 7. The Chair asked all Committee members to declare any relevant interests
 - 7.1. Mr Kamal Balakrishnan, Dr Alex Cale, Mr Michael Chambers, Ms Gail Coster, Dr Prithwiraj Das, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Dr Rubin Minhas, Dr Richard Nicholas, Prof Andrew Renehan, Professor Peter Selby, Dr Paul Tappenden and Dr Judith Wardle all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of arsenic trioxide for treating acute promyelocytic leukaemia [ID446]
- 8. The Chair asked all NICE Staff to declare any 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 arsenic trioxide for treating acute promyelocytic leukaemia [ID446]
- 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 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 arsenic trioxide for treating acute promyelocytic leukaemia [ID446]
 - 9.2. Nigel Russell declared a personal non-specific financial interest as he has participated in advisory boards for Teva
 - 9.2.1. It was agreed that this declaration would not prevent Nigel Russell from participating in this section of the meeting

- 10. The Chair introduced the lead team, Andrew Renehan, Michael Chambers and Judith Ward, who gave presentations on the clinical effectiveness and cost effectiveness of arsenic trioxide for treating acute promyelocytic leukaemia [ID446]
- 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 arsenic trioxide for treating acute promyelocytic leukaemia [ID446]
 - 15.1. The committee decision was based on consensus
- 16. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of brentuximab vedotin for treating CD30-positive Hodgkin's lymphoma (CDF Review of TA446) [ID1366]

Part 1 - Open session

- 17. The Chair welcomed the invited experts: Mariana Bacelar, Steve Edwards, Charlotta Karner, Graham Collins and Kirsty Thomson to the meeting and they introduced themselves to the Committee.
- 18. The Chair welcomed company representatives from Takeda to the meeting.
- 19. The Chair asked all Committee members to declare any relevant interests
 - 19.1. Mr Kamal Balakrishnan, Dr Alex Cale, Mr Michael Chambers, Mr David Chandler, Ms Gail Coster, Dr Prithwiraj Das, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Dr Rubin Minhas, Dr Richard Nicholas, Prof Stephen O'Brien, Prof Andrew Renehan, Dr Paul Tappenden 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 specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of brentuximab vedotin for treating CD30-positive Hodgkin's lymphoma (CDF Review of TA446) [ID1366]

- 19.2. Dr Michael Chambers is noted to be absent for this appraisal due to conflicts as he declared a personal, non-specific, financial interest in working part-time on contract for Takeda
- 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 brentuximab vedotin for treating CD30-positive Hodgkin's lymphoma (CDF Review of TA446) [ID1366]
- 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 brentuximab vedotin for treating CD30-positive Hodgkin's lymphoma (CDF Review of TA446) [ID1366]
 - 21.2. Graham Collins declared a personal non-specific financial interest as he has previously received honoraria for advisory work for Takeda 21.2.1. It was agreed that this declaration would not prevent Graham Collins from participating in this section of the meeting
- 22. The Chair introduced the lead team, David Chandler and Paul Tappenden, who gave presentations on the clinical effectiveness and cost effectiveness of brentuximab vedotin for treating CD30-positive Hodgkin's lymphoma (CDF Review of TA446) [ID1366]
- 23. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
- 24. 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.
- 25. 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

- 26. Discussion on confidential information continued. This information was supplied by the company.
- The Committee continued to discuss the clinical and cost effectiveness of brentuximab vedotin for treating CD30-positive Hodgkin's lymphoma (CDF Review of TA446) [ID1366]

- 27.1. The committee decision was based on consensus
- 28. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of midostaurin for untreated acute myeloid leukaemia [ID894]

Part 1 – Open session

- 29. The Chair welcomed company representatives from Novartis to the meeting.
- 30. The Chair asked all Committee members to declare any relevant interests
 - 30.1. Chair Professor Stephen O'Brien, Mr Kamal Balakrishnan, Dr Alex Cale, Mr Michael Chambers, Mr David Chandler, Ms Gail Coster, Dr Prithwiraj Das, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Dr Rubin Minhas, Dr Richard Nicholas, Prof Andrew Renehan, Professor Peter Selby, Dr Paul Tappenden and Dr Judith Wardle all declared that they knew of no personal specific financial interest, personal non-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 midostaurin for untreated acute myeloid leukaemia [ID894]
- 31. The Chair asked all NICE Staff to declare any relevant interests.
 - 31.1. 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 midostaurin for untreated acute myeloid leukaemia [ID894]
- 32. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests
- 33. 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.
- 34. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
- 35. 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.
- 36. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

- 37. Discussion on confidential information continued. This information was supplied by the company.
- 38. The Committee continued to discuss the clinical and cost effectiveness of midostaurin for untreated acute myeloid leukaemia [ID894]
 - 38.1. The committee decision was based on consensus.
- 39. 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

Thursday 26 April 2018 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT