

Technology Appraisal Committee Meeting (Committee C)

Minutes: Confirmed

Date and Time: Tuesday 31 July 2018, 10am – 5pm

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

Present:	1. Chair Professor Stephen O'Brien 2. Mr Kamal Balakrishnan 3. Dr Alex Cale 4. Mr Michael Chambers 5. Mr David Chandler 6. Ms Gail Coster 7. Dr Natalie Hallas 8. Mr John Hampson 9. Dr Nigel Langford 10. Dr Rubin Minhas 11. Prof Andrew Renahan 12. Dr Peter Selby 13. Dr Paul Tappenden 14. Dr Derek Ward 15. Dr Judith Wardle	Present for all notes Present for all notes
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In attendance:

Helen Knight	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Frances Sutcliffe	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Gemma Barnacle	Project Manager, National Institute for Health and Care Excellence	Present for notes 1 to 17
	Project Manager,	

Stephanie Callaghan	National Institute for Health and Care Excellence	Present for notes 18 to 28
Ismahan Abdullah	Administrator, National Institute for Health and Care Excellence	Present for notes 1 to 23
Pratit Shah	Administrator, National Institute for Health and Care Excellence	Present for all notes
Lorna Dunning	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 18 to 28
Kirsty Pitt	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 17
Nicola Hay	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 18 to 28
Alexandra Filby	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 1 to 17

Non-public attendees:

Lindsay Claxton	Evidence Review Group Representative	Present for notes 6 to 14
Mark Corbett	Evidence Review Group Representative	Present for notes 18 to 25
Ana Duarte	Evidence Review Group Representative	Present for notes 18 to 25
Alexis Llewellyn	Evidence Review Group Representative	Present for notes 6 to 14
Stephen Palmer	Evidence Review Group Representative	Present for notes 18 to 25
Ros Wade	Evidence Review Group Representative	Present for notes 6 to 14
Peter Clark	NHS Commissioning	Present for all notes

	Expert	
Clare Foreman	Commissioning Expert	Present for notes 18 to 25
Steven Knapper	Clinical Expert	Present for notes 6 to 14
Andrew McMillan	Clinical Expert	Present for notes 17 to 25
Priyanka Mehta	Clinical Expert	Present for notes 6 to 14
John Radford	Clinical Expert	Present for notes 17 to 25
Alasdair Rankin	Patient Expert	Present for notes 17 to 25
Phil Reynolds	Patient Expert	Present for notes 17 to 25
Mark Sandford	Patient Expert	Present for notes 6 to 14
Martin Brown	Company representative	Present for notes 18 to 25
Julian Cole	Company representative	Present for notes 18 to 25
Anuraag Kansal	Company representative	Present for notes 6 to 14
Roderick Murphy	Company representative	Present for notes 6 to 14
Carl Boswell	NICE Observer	Present for notes 17 to 28
Sarah Crook	NICE Observer	Present for notes 1 to 17
Carla Deakin	NICE Observer	Present for notes 17 to 28
Sally Doss	NICE Observer	Present for all notes
Henry Edwards	NICE Observer	Present for notes 17 to 28
Alexandra Filby	NICE Observer	Present for notes 17 to 28
Les Hayes	NICE Observer	Present for notes 1 to 28
Fay McCracken	NICE Observer	Present for notes 17 to 28

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 liposomal cytarabine and daunorubicin for untreated acute myeloid leukaemia [ID1225] and axicabtagene ciloleucel for treating diffuse large B-cell lymphoma, mediastinal B-cell lymphoma and follicular lymphoma [ID1115]

2. The Chair informed the Committee of the non-public observers at this meeting: Carl Boswell, Sarah Crook, Carla Deakin, Sally Doss, Henry Edwards, Alexandra Filby, Les Hayes, Linda Landells and Fay McCracken
3. Apologies were received from Professor Andrea Manca, Professor Matt Stevenson, Dr Prithwiraj Das, Dr Richard Nicholas and Professor Robert Walton

Any other Business

4. None

Appraisal of liposomal cytarabine and daunorubicin for untreated acute myeloid leukaemia [ID1225]

Part 1 – Open session

5. The Chair welcomed the invited experts: Peter Clark, Lindsay Claxton, Steven Knapper, Alexis Llewellyn, Priyanka Mehta and Mark Sandford, and Ros Wade to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Jazz Pharmaceuticals to the meeting.
7. The Chair asked all Committee members 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 liposomal cytarabine and daunorubicin for untreated acute myeloid leukaemia
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 liposomal cytarabine and daunorubicin for untreated acute myeloid leukaemia
9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 9.1. Mark Sandford 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 liposomal cytarabine and daunorubicin for untreated acute myeloid leukaemia
 - 9.2. Dr Priyanka Mehta declared a personal non-specific financial interest as she has received honoraria payments from Jazz Pharmaceuticals for advisory board and training/teaching events

- 9.2.1. It was agreed that this declaration would not prevent Dr Priyanka Mehta from participating in this section of the meeting
- 9.3. Dr Steven Knapper declared a personal non-specific financial interest as he is receiving support from Jazz Pharmaceuticals for attending American Society of Hematology 2018
 - 9.3.1. It was agreed that this declaration would not prevent Dr Steven Knapper from participating in this section of the meeting
10. The Chair introduced the lead team, John Hampson, Natalie Hallas and David Chandler who gave presentations on the clinical effectiveness and cost effectiveness of the appraisal of liposomal cytarabine and daunorubicin for untreated acute myeloid leukaemia
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 liposomal cytarabine and daunorubicin for untreated acute myeloid leukaemia
 - 15.1. The committee decision was based on consensus.
16. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of axicabtagene ciloleucel for treating diffuse large B-cell lymphoma, mediastinal B-cell lymphoma and follicular lymphoma [ID1115]

Part 1 – Open session

17. The Chair welcomed the invited experts: Peter Clark, Mark Corbett, Ana Duarte, Clare Foreman, Andrew McMillan, Stephen Palmer, John Radford, Alasdair Rankin and Phil Reynolds to the meeting and they introduced themselves to the Committee.
18. The Chair welcomed company representatives from Kite, a Gilead company to the meeting.
19. The Chair asked all Committee members to declare any relevant interests

19.1. Mr Kamal Balakrishnan, Dr Alex Cale, Mr David Chandler, Ms Gail Coster, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Dr Rubin Minhas, Dr Paul Tappenden, Dr Derek Ward 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 axicabtagene ciloleucel for treating diffuse large B-cell lymphoma, mediastinal B-cell lymphoma and follicular lymphoma

19.2. Professor Stephen O'Brien declared a non-personal specific financial interest related to his involvement in research at Newcastle University, for the SPIRIT 2 Trial in CML funded by BMS a comparator company. In addition his organisation is bidding to provide CAR-t cell therapy.

19.2.1. It was agreed that this declaration would not prevent Professor Stephen O'Brien from participating in this section of the meeting.

19.3. Professor Andrew Renahan declared a non-personal specific financial interest as his organisation is bidding to provide CAR-t cell therapy.

19.3.1. It was agreed that this declaration would not prevent Professor Andrew Renahan from participating in this section of the meeting.

19.4. Dr Peter Selby declared a non-personal specific financial interest as his organisation is bidding to provide CAR-t cell therapy.

19.4.1. It was agreed that this declaration would not prevent Dr Peter Selby from participating in this section of the meeting

19.5. Dr Michael Chambers declared a non-personal specific financial interest as he participated in an advisory board for Roche, a comparator company in an unrelated area

19.5.1. It was agreed that this declaration would not prevent Michael Chambers from participating in this section of the meeting.

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 axicabtagene ciloleucel for treating diffuse large B-cell lymphoma, mediastinal B-cell lymphoma and follicular lymphoma

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

21.1. Peter Clark, Clare Foreman and Phil Reynolds 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 axicabtagene ciloleucel for treating diffuse large B-cell lymphoma, mediastinal B-cell lymphoma and follicular lymphoma

- 21.2. Professor Andrew McMillan declared a personal non-specific financial interest as he attended a Novartis advisory board on the use of a different CAR T cell therapy product in acute lymphoblastic leukaemia. He has also declared a non-personal financial interest as he is a member of a trial steering committee for AUTOLUS, another CAR T cell company.
 - 21.2.1. It was agreed that these declaration would not prevent Professor Andrew McMillan from participating in this section of the meeting
- 21.3. Professor John Radford declared a personal non-specific financial interest as he has received payments from Takeda for advisory board involvement, advice and presentations. He also declared a personal non-specific family interest as family have shareholdings in AstraZeneca and GlaxoSmithKline. He also declared a non-personal financial interest as he has receives research funding from commercial organisations routed through the University of Manchester or the Christie NHS Foundation Trust.
 - 21.3.1. It was agreed that these declaration would not prevent Professor John Radford from participating in this section of the meeting
- 21.4. Dr Alasdair Rankin declared a personal non-specific non-financial interest as he has patient of clinical trial that is funded by industry.
 - 21.4.1. It was agreed that these declaration would not prevent Professor John Radford from participating in this section of the meeting

22. The Chair introduced the lead team, Dr Nigel Langford, Mr Michael Chambers and Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of the appraisal of axicabtagene ciloleucel for treating diffuse large B-cell lymphoma, mediastinal B-cell lymphoma and follicular lymphoma
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.

27. The Committee continued to discuss the clinical and cost effectiveness of axicabtagene ciloleucel for treating diffuse large B-cell lymphoma, mediastinal B-cell lymphoma and follicular lymphoma

27.1. The committee decision was based on consensus.

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

Date, time and venue of the next meeting

28. Wednesday 22 August 2018 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT