

## Technology Appraisal Committee Meeting (Committee C)

**Minutes:** Confirmed

**Date and Time:** Tuesday 16 May 2017, 10:00 to 18:00

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

<b>Present:</b>	1. Chair Professor Andrew Stevens	Present for all notes
	2. Professor Kathryn Abel	Present for all notes
	3. Mr Kamal Balakrishnan	Present for all notes
	4. Mr Michael Chambers	Present for all notes
	5. Mr David Chandler	Present for all notes
	6. Mrs Gail Coster	Present for all notes
	7. Dr Prithwiraj Das	Present for all notes
	8. Mr John P Hampson	Present for all notes
	9. Dr Nigel Langford	Present for all notes
	10. Professor Andrea Manca	Present for all notes
	11. Dr Iain Miller	Present for all notes
	12. Professor Andrew Renehan	Present for all notes
	13. Professor Stephen O'Brien	Present for all notes
	14. Professor Peter Selby	Present for all notes
	15. Professor Matt Stevenson	Present for notes 4 to 26 and 39 to 49
	16. Dr Paul Tappenden	Present for all notes
	17. Mr Robert Walton	Present for all notes
	18. Dr Judith Wardle	Present for all notes

### In attendance:

Meindert Boysen	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
Stephanie Yates	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Liga Kremere	Administrator, National	Present for note 1 to 26

Institute for Health and  
Care Excellence

Emily Richards	Assistant Project Manager, National Institute for Health and Care Excellence	Present for notes 27 to 49
Marcela Haasova	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 4 to 14
Sally Doss	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 4 to 14
Sana Khan	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 15 to 26
Nicola Hay	Technical Advisor, National Institute for Health and Care Excellence	Present for notes 15 to 26
Helen Powell	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 27 to 35
Alex Filby	Technical Advisor, National Institute for Health and Care Excellence	Present for notes 27 to 49
Irina Voicechovskaja	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 39 to 49

**Non-public attendees:**

Ailsa Bosworth	Patient Expert	Present for notes 27 to 35
Peter Clark	Commissioning Expert	Present for notes 4 to 26
Adele Fielding	Clinical Expert	Present for notes 4 to 11
Dr Christopher Fox	Clinical Expert	Present for notes 15 to 23
Dr Chris Holroyd	Clinical Expert	Present for notes 27 to 35
Jennie Jones	Patient Expert	Present for notes 27 to 35
Chloe Pinder	Patient Expert	Present for notes 4 to 11
Professor Peter Taylor	Clinical Expert	Present for notes 27 to 35
Marcus Williams	Patient Expert	Present for notes 15 to 23

Dwayne Boyers	ERG representative	Present for notes 15 to 23
Edward Cox	ERG representative	Present for notes 4 to 11
Moir Cruishank	ERG representative	Present for notes 15 to 23
Susan Griffin	ERG representative	Present for notes 4 to 11
Graham Scotland	ERG representative	Present for notes 15 to 23
Dr Emma Simpson	ERG representative	Present for notes 27 to 35
Professor Matt Stevenson	ERG representative	Present for notes 27 to 35
Ros Wade	ERG representative	Present for notes 4 to 11
Kristina Dietz	NICE Observer	Present for all notes
Steve Estevao	NICE Observer	Present for all notes
Leslie Hayes	NICE Observer	Present for all notes
Lydia Shears	NICE Observer	Present for notes 4 to 38
Ellise Warren	NICE Observer	Present for all notes

## 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 inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia, brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma, baricitinib for moderate to severe rheumatoid arthritis and holoclax for treating limbal stem cell deficiency after eye burns.
2. The Chair informed the Committee of the non-public observers at this meeting: John Borrill, Kristina Dietz, Steve Estevao, Leslie Hayes, Lydia Shears, Ellise Warren

### Any other business

3. None

### Appraisal of inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia [ID893]

#### Part 1 – Open session

4. The Chair welcomed the invited experts: Peter Clark, Edward Cox, Adele Fielding, Susan Griffin, Chloe Pinder and Ros Wade to the meeting and they introduced themselves to the Committee.
5. The Chair welcomed company representatives from Pfizer to the meeting.
6. The Chair asked all Committee members to declare any relevant interests
  - 6.1. Chair Professor Andrew Stevens, Professor Kathryn Abel, Mr Kamal Balakrishnan, Mr Michael Chambers, Mr David Chandler, Gail Coster, Dr Prithwiraj Das, Mr John P Hampson, Dr Nigel Langford, Dr Iain Miller, Professor Andrew Renehan, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Mr Robert Walton, 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 inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.

6.2. Professor Andrea Manca declared a personal non-specific financial interest as he has carried out paid consultancy for Pfizer by participating in an advisory board for a product in a different disease area. Professor Andrea Manca declared a personal non-specific financial interest co-applicant in the European Commission (EC) H2020 IMI2 funded project HARMONY. This is a public-private partnership and NOVARTIS is one of the participants for which Andrea's organisation receives funding towards his salary.

6.2.1. It was agreed that this declaration would not prevent Professor Andrea Manca from participating in this section of the meeting.

6.2.2. Professor Stephen O'Brien declared a personal non-specific financial interest as his University and/or NHS Trust has received research funding for clinical trial work from the following companies: Pfizer, Novartis and Bristol-Myers Squibb.

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

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

6.4. 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 inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.

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 inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.

7.2. Adele Fielding declared a personal non-specific financial interest she has sat on advisory boards for Pfizer.

7.2.1. It was agreed that this declaration would not prevent Adele Fielding from participating in this section of the meeting

8. The Chair introduced the lead team, John Hampson, Michael Chambers and David Chande who gave presentations on the clinical effectiveness and cost effectiveness of inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.

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. Discussion on confidential information continued. This information was supplied by the company.
13. The Committee continued to discuss the clinical and cost effectiveness of inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.
  - 13.1. The committee decision was based on consensus.
14. The Committee instructed the technical team to prepare the Appraisal Consultation Document in line with their decisions.

## **Appraisal of brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma [ID512]**

## **Part 1 – Open session**

15. The Chair welcomed the invited experts: Dwayne Boyers, Peter Clark, Moira Cruishank, Christopher Fox and Graham Scotland to the meeting and they introduced themselves to the Committee.
16. The Chair welcomed company representatives from Takeda UK to the meeting.
17. The Chair asked all Committee members to declare any relevant interests
  - 17.1. Chair Professor Andrew Stevens, Professor Kathryn Abel, Mr Kamal Balakrishnan, Mr David Chandler, Gail Coster, Dr Prithwiraj Das, Mr John P Hampson, Dr Nigel Langford, Dr Iain Miller, Professor Andrew Renehan, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Mr Robert Walton, 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 brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.
  - 17.2. Professor Andrea Manca declared a personal non-specific financial interest as co-applicant in the European Commission (EC) H2020 IMI2 funded project HARMONY. This is a public-private partnership and Takeda is one of the participants for which Andrea’s organisation receives funding towards his salary.
    - 17.2.1. It was agreed that this declaration would not prevent Professor Andrea Manca from participating in this section of the meeting.

- 17.3. Professor Stephen O'Brien declared a personal non-specific financial interest as his university had previously received research funding for clinical trials from Ariad which was taken over by Takeda UK in February 2017.
- 17.3.1. It was agreed that this declaration would not prevent Professor Stephen O'Brien from participating in this section of the meeting.
- 17.4. Mr Michael Chambers declared a personal non-specific financial interest as he has participated in advisory boards for the IMI Get Real project, for which Takeda UK is a partner organisation.
- 17.4.1. It was agreed that this declaration would not prevent Mr Michael Chambers from participating in this section of the meeting.
18. The Chair asked all NICE Staff to declare any 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 brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.
19. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
- 19.1. 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 relapsed or refractory systemic anaplastic large cell lymphoma.
- 19.2. Dr Christopher Fox declared a personal non specific financial interest as he has presented and received payment for participating in advisory boards for Takeda.
- 19.2.1. It was agreed that this declaration would not prevent Dr Christopher Fox from participating in this section of the meeting
20. The Chair introduced the lead team, Dr Robert Walton, Mr Iain Miller and Dr Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.
21. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
22. 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.

23. 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**

24. Discussion on confidential information continued. This information was supplied by the company.
25. The Committee continued to discuss the clinical and cost effectiveness of brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.

25.1. The committee decision was based on consensus.

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

## **Appraisal of baricitinib for moderate to severe rheumatoid arthritis [ID979]**

### **Part 1 – Open session**

27. The Chair welcomed the invited experts: Ailsa Bosworth, Jennie Jones, Dr Chris Holroyd, Emma Simpson, Matt Stevenson, Professor Peter Taylor to the meeting and they introduced themselves to the Committee.
28. The Chair welcomed company representatives from Eli Lilly and Company Limited to the meeting.
29. The Chair asked all Committee members to declare any relevant interests
- 29.1. Chair Professor Andrew Stevens, Professor Kathryn Abel, Mr Kamal Balakrishnan, Mr Michael Chambers, Mr David Chandler, Gail Coster, Dr Prithwiraj Das, Mr John P Hampson, Dr Nigel Langford, Professor Andrea Manca, Dr Iain Miller, Professor Andrew Renehan, Professor Stephen O'Brien, Dr Peter Selby, Dr Paul Tappenden, Mr Robert Walton, 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 baricitinib for moderate to severe rheumatoid arthritis.
- 29.2. It was noted that Committee member Professor Matt Stevenson is serving as an ERG representative and were therefore absent from the Committee
30. The Chair asked all NICE Staff to declare any relevant interests.
- 30.1. 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 baricitinib for moderate to severe rheumatoid arthritis.
31. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.

- 31.1. Jennie Jones 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 baricitinib for moderate to severe rheumatoid arthritis.
- 31.2. Ailsa Bosworth declared a personal non-specific financial interest as her organisation has received funding grants from the pharmaceutical industry.
- 31.2.1. It was agreed that this declaration would not prevent Ailsa Bosworth from participating in this section of the meeting
- 31.3. Dr Chris Holroyd declared a personal non-specific financial interest as he has received funding from industry for lectures.
- 31.3.1. It was agreed that this declaration would not prevent Dr Chris Holroyd from participating in this section of the meeting.
- 31.4. Professor Peter Taylor declared a personal non-specific financial interest as he has received research grants from industry and funding for consultancy work.
- 31.4.1. It was agreed that this declaration would not prevent Professor Peter Taylor from participating in this section of the meeting.
32. The Chair introduced the lead team, David Chandler, Professor Stephen O'Brien and Professor Andrew Renehan who gave presentations on the clinical effectiveness and cost effectiveness of baricitinib for moderate to severe rheumatoid arthritis.
33. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
34. 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.
35. 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**

36. Discussion on confidential information continued. This information was supplied by the company.
37. The Committee continued to discuss the clinical and cost effectiveness of baricitinib for moderate to severe rheumatoid arthritis.
- 37.1. The committee decision was based on consensus.
38. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.



## **Appraisal of holoclar for treating limbal stem cell deficiency after eye burns [ID899]**

### **Part 1 – Open session**

39. The Chair welcomed company representatives from Chiesi Ltd to the meeting.
40. The Chair asked all Committee members to declare any relevant interests
  - 40.1. Chair Professor Andrew Stevens, Professor Kathryn Abel, Mr Kamal Balakrishnan, Mr Michael Chambers, Mr David Chandler, Gail Coster, Dr Prithwiraj Das, Mr John P Hampson, Dr Nigel Langford, Professor Andrea Manca, Dr Iain Miller, Professor Andrew Renehan, Professor Stephen O'Brien, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Mr Robert Walton, 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 holoclar for treating limbal stem cell deficiency after eye burns.
41. The Chair asked all NICE Staff to declare any relevant interests.
  - 41.1. 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 Holoclar for treating limbal stem cell deficiency after eye burns.
42. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
  - 42.1. 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 Holoclar for treating limbal stem cell deficiency after eye burns.
43. 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.
44. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
45. 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.
46. 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**

- 47. Discussion on confidential information continued. This information was supplied by the company.
- 48. The Committee continued to discuss the clinical and cost effectiveness of Holoclar for treating limbal stem cell deficiency after eye burns
- 49. 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**

- 50. Wednesday 14 June 2017 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.