CDF Rapid Reconsideration Appraisal Committee Meeting

Minutes: Unconfirmed

Date and Time: Tuesday 29 November 2016, 10:00am to 17:00pm

Venue: National Institute for Health and Care Excellence
10 Spring Gardens
London
SW1A 2BU

Present:
1. Chair Professor Andrew Stevens Present for notes 1 to 27
2. Chair Dr Amanda Adler Present for notes 28 to 38
3. Dr Jeff Aronson Present for all notes
4. Professor David Bowen Present for all notes
5. Prof John Cairns Present for all notes
6. Mark Chapman Present for all notes
7. Prof Rachel Elliott Present for all notes
8. Prof Gary McVeigh Present for all notes
9. Prof Stephen O’Brien Present for all notes
10. Dr Anna O’Neill Present for all notes
11. Christopher O’Regan Present for all notes
12. Dr Brian Shine Present for all notes
13. Dr Matt Stevenson Present for all notes
14. Judith Wardle Present for all notes
15. Nigel Westwood 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 notes 1 to 15 and notes 28 to 38

Janet Robertson Associate Director, National Institute for Health and Care Excellence Present for notes 16 to 27

Professor Carole Longson Centre Director, National Institute for Health and Care Excellence Present for all notes
<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Present for Notes</th>
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<tbody>
<tr>
<td>Jenna Dilkes</td>
<td>Project Manager, National Institute for Health and Care Excellence</td>
<td>1 to 15</td>
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<tr>
<td>Emily Richards</td>
<td>Assistant Project Manager, National Institute for Health and Care Excellence</td>
<td>1 to 15</td>
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<tr>
<td>Marcela Haasova</td>
<td>Technical Lead, National Institute for Health and Care Excellence</td>
<td>1 to 15</td>
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<td>Helen Powell</td>
<td>Technical Lead, National Institute for Health and Care Excellence</td>
<td>16 to 27</td>
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<td>Martyn Burke</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>28 to 38</td>
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<tr>
<td>Wendy Gidman</td>
<td>Technical Lead, National Institute for Health and Clinical Excellence</td>
<td>28 to 38</td>
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<tr>
<td>Mariana Bacelar</td>
<td>ERG Representative</td>
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<td>Steve Edwards</td>
<td>ERG Representative</td>
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<td>Hazel Squires</td>
<td>ERG Representative</td>
<td>16 to 24</td>
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<td>Sabine Grimm</td>
<td>ERG Representative</td>
<td>28 to 34</td>
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<td>Inigo Bermejo</td>
<td>ERG Representative</td>
<td>28 to 34</td>
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<tr>
<td>Dr Fiona Thistlewaite</td>
<td>Clinical Expert</td>
<td>1 to 12</td>
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<td>Dr Naveed Sarwar</td>
<td>Clinical Expert</td>
<td>1 to 12</td>
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<td>Lisa Barraclough</td>
<td>Clinical Expert</td>
<td>16 to 24</td>
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<td>Dr Helena Earl</td>
<td>Clinical Expert</td>
<td>16 to 24</td>
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<td>Melanie Johnston</td>
<td>Patient Expert</td>
<td>16 to 24</td>
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<td>Dr Vivienne Ashley</td>
<td>Patient Expert</td>
<td>16 to 24</td>
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<td>Professor Daniel Palmer</td>
<td>Clinical Expert</td>
<td>28 to 34</td>
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<tr>
<td>Peter Clark</td>
<td>CDF Clinical Lead</td>
<td>1 to 15</td>
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Non-public observers:

Helen Barnett      NICE Observer      Present for all notes
Heidi Livingstone  NICE Observer      Present for notes 16 to 24
Maroulla Whiteley  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 Everolimus for the second-line treatment of metastatic renal cell carcinoma (review of TA219), Trastuzumab emtansine for the treatment of locally advanced or metastatic HER2-positive breast cancer after treatment with trastuzumab and a taxane (review of TA371) and Sorafenib for advanced hepatocellular carcinoma (review of TA189).

2. Apologies were received from Gail Coster, Andrew England, Susan Griffin, Professor Eugene Milne and Professor Femi Oyebode.

Any other Business

3. None

Appraisal of Everolimus for the second-line treatment of metastatic renal cell carcinoma (review of TA219)

Part 1 – Open session

4. The Chair welcomed the invited experts: Dr Fiona Thistlewaite, Dr Naveed Sarwar and Peter Clark to the meeting and they introduced themselves to the Committee.

5. The Chair welcomed company representatives from Novartis to the meeting.

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

   6.1. Professor Andrew Stevens, Dr Jeff Aronson, Professor David Bowen, Professor John Cairns, Mark Chapman, Professor Rachel Elliot, Professor Gary McVeigh, Professor Stephen O’Brien, Dr Anna O’Neill, Christopher O’Regan, Dr Brian Shine, Dr Matt Stevenson, Judith Wardle and Nigel Westwood 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 Everolimus for the second-line treatment of metastatic renal cell carcinoma (review of TA219).

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 Everolimus for the second-line treatment of metastatic renal cell carcinoma (review of TA219).

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 Everolimus for the second-line treatment of metastatic renal cell carcinoma (review of TA219).


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

11. 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.

12. 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

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


14.1. The committee decision was based on consensus.

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

Appraisal of Trastuzumab emtansine for the treatment of locally advanced or metastatic HER2-positive breast cancer after treatment with trastuzumab and a taxane (review of TA371)
Part 1 – Open session

16. The Chair welcomed the invited experts: Lisa Barraclough, Dr Helena Earl, Melanie Johnston, Dr Vivienne Ashley and Peter Clark to the meeting and they introduced themselves to the Committee.

17. The Chair welcomed company representatives from Roche to the meeting.

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

18.1. Professor Andrew Stevens, Dr Jeff Aronson, Professor David Bowen, Professor John Cairns, Mark Chapman, Professor Rachel Elliot, Professor Gary McVeigh, Professor Stephen O’Brien, Dr Anna O’Neill, Christopher O’Regan, Dr Brian Shine, Dr Matt Stevenson, Judith Wardle and Nigel Westwood 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 Trastuzumab emtansine for the treatment of locally advanced or metastatic HER2-positive breast cancer after treatment with trastuzumab and a taxane (review of TA371).

19. The Chair asked all NICE Staff to declare any 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 Trastuzumab emtansine for the treatment of locally advanced or metastatic HER2-positive breast cancer after treatment with trastuzumab and a taxane (review of TA371).

20. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their 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 trastuzumab emtansine for the treatment of locally advanced or metastatic HER2-positive breast cancer after treatment with trastuzumab and a taxane (review of TA371).

21. The Chair gave a presentation on the clinical effectiveness and cost effectiveness of trastuzumab emtansine for the treatment of locally advanced or metastatic HER2-positive breast cancer after treatment with trastuzumab and a taxane (review of TA371).

22. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
23. 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.

24. 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

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

26. The Committee continued to discuss the clinical and cost effectiveness of Trastuzumab emtansine for the treatment of locally advanced or metastatic HER2-positive breast cancer after treatment with trastuzumab and a taxane (review of TA371).

26.1. The committee decision was based on consensus.

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

Appraisal of Sorafenib for advanced hepatocellular carcinoma (review of TA189)

Part 1 – Open session

28. The Chair welcomed the invited experts: Professor Daniel Palmer to the meeting and they introduced themselves to the Committee.

29. The Chair welcomed company representatives from Bayer to the meeting.

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

30.1. Dr Amanda Adler, Dr Jeff Aronson, Professor David Bowen, Professor John Cairns, Mark Chapman, Professor Rachel Elliot, Professor Gary McVeigh, Professor Stephen O’Brien, Dr Anna O’Neill, Christopher O’Regan, Dr Brian Shine, Dr Matt Stevenson, Judith Wardle and Nigel Westwood 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 sorafenib for advanced hepatocellular carcinoma (review of TA189).

31. 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.

32. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
33. 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.

34. 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**

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

36. The Committee continued to discuss the clinical and cost effectiveness of sorafenib for advanced hepatocellular carcinoma (review of TA189).

36.1. A vote was taken. The options were:
Option 1: Yes in routine commissioning
Option 2: No in routine commissioning
Option 3: No in routine commissioning, Yes in CDF

Details of the result of this discussion will be included in the confirmed version of these minutes, which will be published after the publication of all decisions taken at this Committee meeting.

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

**Date, time and venue of the next meeting**

38. Wednesday 1 February 2017 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.