

## **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

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

Jenna Dilkes	Project Manager, National Institute for Health and Care Excellence	
Emily Richards	Assistant Project Manager, National Institute for Health and Care Excellence	Present for notes 1 to 15
Marcela Haasova	Technical Lead, National Institute for Health and Care Excellence	Present for notes 1 to 15
Helen Powell	Technical Lead, National Institute for Health and Care Excellence	Present for notes 16 to 27
Martyn Burke	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 28 to 38
Wendy Gidman	Technical Lead National Institute for Health and Clinical Excellence	Present for notes 28 to 38
Mariana Bacelar	ERG Representative	Present for notes 1 to 12
Steve Edwards	ERG Representative	Present for notes 1 to 12
Hazel Squires	ERG Representative	Present for notes 16 to 24
Sabine Grimm	ERG Representative	Present for notes 28 to 34
Indigo Bermejo	ERG Representative	Present for notes 28 to 34
Dr Fiona Thistlewaite	Clinical Expert	Present for notes 1 to 12
Dr Naveed Sarwar	Clinical Expert	Present for notes 1 to 12
Lisa Barraclough	Clinical Expert	Present for notes 16 to 24
Dr Helena Earl	Clinical Expert	Present for notes 16 to 24
Melanie Johnston	Patient Expert	Present for notes 16 to 24
Dr Vivienne Ashley	Patient Expert	Present for notes 16 to 24
Professor Daniel Palmer	Clinical Expert	Present for notes 28 to 34
Peter Clark	CDF Clinical Lead	Present for notes 1 to 15

**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).
9. The Chair gave a presentation on the clinical effectiveness and cost effectiveness 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. The Committee continued to discuss the clinical and cost effectiveness of Everolimus for the second-line treatment of metastatic renal cell carcinoma (review of TA219).
  - 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.