Technology Appraisal Committee Meeting (CDF Committee)

Minutes: Unconfirmed

Date and Time: Tuesday 29 September, 10.00am to 4.30pm

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

Present:
1. Chair Professor Andrew Stevens Present for notes 1 to 27
2. Chair Amada Adler Present for notes 28 to 44
3. Dr Jeff Aronson Present for all notes
4. Dr Matthew Bradley Present for all notes
5. Professor John Cairns Present for all notes
6. Mark Chapman Present for all notes
7. Gail Coster Present for all notes
8. Dr Ian Davidson Present for all notes
9. Dr Nigel De Kare Silver Present for all notes
10. Andrew England Present for all notes
11. Professor Rachel Elliot Present for all notes
12. Susan Griffin Present for notes 1 to 39
13. Dr Anna O’Neill Present for all notes
14. Christopher O’Regan Present for all notes
15. Malcolm Oswald Present for all notes
16. Dr Brian Shine Present for all notes
17. Dr Matt Stevenson Present for all notes
18. Dr Nicky Welton Present for all notes
19. Nigel Westwood Present for all notes

In attendance:

Meindert Boysen Programme Director, National Institute for Health and Care Excellence Present for all notes

Janet Robertson Associate Director, National Institute for Health and Care Excellence Present for notes 1 to 15

Helen Knight Associate Director, National Institute for Health and Care Excellence Present for notes 28 to 39

Jenna Dilkes Project Manager, National Institute for Present for all notes
Health and Care Excellence

Carl Jackson  Administrator, National Institute for Health and Care Excellence  Present for all notes

Helen Powell  Technical Analyst, National Institute for Health and Care Excellence  Present for notes 1 to 15

Thomas Strong  Technical Analyst, National Institute for Health and Care Excellence  Present for notes 16 to 27

Sally Doss  Technical Adviser, National Institute for Health and Care Excellence  Present for notes 28 to 39

Marcela Haasova  Technical Analyst, National Institute for Health and Care Excellence  Present for notes 28 to 44 (Observer for notes 40 to 44)

Martyn Burke  Technical Adviser, National Institute for Health and Clinical Excellence  Present for notes 40 to 44

Adrian Bagust  ERG Representative  Present for notes 1 to 15

Claire Rothery  ERG Representative  Present for notes 16 to 27

Stephen Palmer  ERG Representative  Present for notes 28 to 39

Mathilde Peron  ERG Representative  Present for notes 28 to 39

Dr Joseph Sacco  Clinical Expert  Present for notes 1 to 15

Dr Martin Forster  Clinical Expert  Present for notes 1 to 15

Lesley Holland  Patient Expert  Present for notes 28 to 39

Jesme Fox  Patient Expert  Present for notes 28 to 39

Professor Andrew Nicholson  Clinical Expert  Present for notes 28 to 39

Non-public observers:

Helen Barnett  NICE Observer  Present for notes 1 to 27
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 Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (review of TA172), Dasatinib for the first-line treatment of chronic myeloid leukaemia (part review of TA251), Crizotinib for previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene (review of TA296) and Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA395).

2. Apologies were received from Professor Eugene Milne and Professor Femi Oyebode.

Any other Business

3. None

Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (review of TA172),

Part 1 – Open session

4. The Chair welcomed the invited experts: Adrian Bagust, Dr Joseph Sacco and Dr Martin Foster to the meeting and they introduced themselves to the Committee.

5. The Chair welcomed company representatives from Merck Sharp & Dohme to the meeting.

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

6.1. Professor Andrew Stevens, Dr Jeff Aronson, Dr Matthew Bradley, Professor John Cairns, Mark Chapman, Gail Coster, Dr Ian Davidson, Dr Nigel De Kare Silver, Andrew England, Professor Rachel Elliot, Susan Griffin, Dr Anna O’Neill, Christopher O’Regan, Malcolm Oswald, Dr Brian Shine, Dr Matt Stevenson, Dr Nicky Welton, 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 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 Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (review of TA172).

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 Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (review of TA172).

8. The Chair asked the (ERG and invited experts, not including observers) to declare any relevant interests.

8.1. Adrian Bagust and Dr Martin Foster 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 Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (review of TA172).

8.2. Dr Joseph Sacco declared a personal financial interest as he has received travel and conference expenses and an honorarium from Bristol Myers Squibb. He has also received consultancy fees from both Amgen and Immunocore. These interests do not relate to the subject under discussion and are non-specific according to NICE definitions.

8.2.1. It was agreed that this declaration would not prevent Dr Joseph Sacco from participating in this section of the meeting.

9. The Chair gave presentations on the clinical effectiveness and cost effectiveness of Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (review of TA172).

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 Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (review of TA172).

14.1. The committee decision was based on consensus.
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 Dasatinib for treating imatinib-resistant chronic myeloid leukaemia and for people for whom treatment with imatinib has failed because of intolerance (part review TA241) and Dasatinib for the first-line treatment of chronic myeloid leukaemia (part review of TA251)**

**Part 1 – Open session**

16. The Chair welcomed the invited expert: Claire Rothery to the meeting and they introduced themselves to the Committee.

17. The Chair welcomed company representatives from Bristol Myers Squibb to the meeting.

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

18.1. Professor Andrew Stevens, Dr Jeff Aronson, Dr Matthew Bradley, Professor John Cairns, Mark Chapman, Gail Coster, Dr Ian Davidson, Dr Nigel De Kare Silver, Andrew England, Professor Rachel Elliot, Susan Griffin, Dr Anna O’Neill, Christopher O’Regan, Malcolm Oswald, Dr Brian Shine, Dr Matt Stevenson, Dr Nicky Welton, 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 Dasatinib for the first-line treatment of chronic myeloid leukaemia (part review of TA251).

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 Dasatinib for the first-line treatment of chronic myeloid leukaemia (part review of TA251).

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 Dasatinib for the first-line treatment of chronic myeloid leukaemia (part review of TA251).

21. The Chair gave presentations on the clinical effectiveness and cost effectiveness of Dasatinib for the first-line treatment of chronic myeloid leukaemia (part review of TA251).
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 Dasatinib for the first-line treatment of chronic myeloid leukaemia (part review of TA251).

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 Crizotinib for previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene (review of TA296)**

**Part 1 – Open session**

28. The Chair welcomed the invited expert: Stephen Palmer, Mathilde Peron, Lesley Holland, Jesme Fox, Professor Andrew Nicholson to the meeting and they introduced themselves to the Committee.

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

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

30.1. Dr Amanda Adler, Dr Jeff Aronson, Dr Matthew Bradley, Professor John Cairns, Mark Chapman, Gail Coster, Dr Ian Davidson, Dr Nigel De Kare Silver, Andrew England, Professor Rachel Elliot, Susan Griffin, Dr Anna O’Neill, Christopher O’Regan, Malcolm Oswald, Dr Brian Shine, Dr Matt Stevenson, Dr Nicky Welton, 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 Crizotinib for previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene (review of TA296).

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 Crizotinib for previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene (review of TA296).

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

32.1. Stephen Palmer, Mathilde Peron and Professor Andrew Nicholson 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 Crizotinib for previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene (review of TA296).

32.2. Jesme Fox declared a non-personal pecuniary interest as her employer; The Roy Castle Lung Cancer Foundation (RCLCF) has received grants from multiple pharmaceutical and commercial businesses. These have been for specified projects (eg, Conference organisation, patient information leaflets etc.). She has presented at many conferences and participated in several advisory boards, organised by multiple pharmaceutical companies – In lieu of her time, donations have been given to the company to RCLCF. At no time has she personally accepted honorarium.

32.2.1. It was agreed that this declaration would not prevent Jesme Fox from participating in this section of the meeting.

32.3. Professor Andrew Nicholson declared a personal financial interest as he has received payment as a consultant for advisory boards for Pfizer.

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

33. The Chair gave presentations on the clinical effectiveness and cost effectiveness of Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck (review of TA172).

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.

Part 2 – Closed session
Discussion on confidential information continued. This information was supplied by the company.

The Committee continued to discuss the clinical and cost effectiveness of Crizotinib for previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene (review of TA296).

40.1 The committee decision was based on consensus.

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 Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA395).

Closed session - (No assessment group/ERG, experts and company representative present. This was a private discussion between NICE staff and the committee members.

The Chair asked all Committee members to declare any relevant interests

40.1. Dr Amanda Adler, Dr Jeff Aronson, Dr Matthew Bradley, Professor John Cairns, Mark Chapman, Gail Coster, Dr Ian Davidson, Dr Nigel De Kare Silver, Andrew England, Professor Rachel Elliot, Dr Anna O’Neill, Christopher O’Regan, Malcolm Oswald, Dr Brian Shine, Dr Matt Stevenson, Dr Nicky Welton, 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 in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA395).

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 Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA395).

The Chair gave presentations on the clinical effectiveness and cost effectiveness of Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA395).

The Committee discussed the clinical and cost effectiveness of Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA395).
40.2 The committee decision was based on consensus.

44. 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

45. Tuesday 29 November 2016 10:00am until 17:00pm at NICE, 10 Spring Gardens, London, SW1A 2BU