Technology Appraisal Committee Meeting (Committee B)

Minutes: Confirmed

Date and Time: Thursday 10 May 2018, 10am to 6pm

Venue: 10 Spring Gardens
London
SW1A 2BU

Present:
1. Dr Amanda Adler (Chair) Present for all notes
2. Dr Sanjeev Patel (Vice-Chair) Present for all notes
3. Mr Mark Chapman Present for all notes
4. Ms Susan Faulds Present for all notes
5. Dr Mark Glover Present for all notes
6. Mr Richard Hoddes Present for all notes
7. Dr Mona Johnson Present for all notes
8. Dr Nicholas Latimer Present for notes 20 to 69
9. Mr Christopher O'Regan Present for all notes
10. Professor Stephen Palmer Present for all notes
11. Dr Stephen Smith Present for all notes
12. Mr William Turner Present for all notes
13. Professor Nicky Welton Present for all notes
14. Mr Nigel Westwood Present for all notes
15. Professor Sarah Wild Present for all notes
16. Dr Stuart Williams Present for all notes

In attendance:

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

Melinda Goodall Associate Director, National Institute for Health and Care Excellence Present for all notes

Jeremy Powell Project Manager, National Institute for Health and Care Excellence Present for all notes

Sandra Aleknavice Administrator, National Institute for Health and Care Excellence Present for all notes

Thomas Strong Technical Analyst, National Institute for Present for notes 1 to 32
Ahmed Elsada  Technical Adviser, National Institute for Health and Clinical Excellence  Present for notes 1 to 32

Alan Lamb  Technical Analyst, National Institute for Health and Care Excellence  Present for notes 1 to 32

Mary Hughes  Technical Analyst, National Institute for Health and Care Excellence  Present for notes 33 to 45

Jasdeep Hayre  Technical Adviser, National Institute for Health and Clinical Excellence  Present for notes 33 to 56

Sharlene Ting  Technical Analyst, National Institute for Health and Care Excellence  Present for notes 46 to 56

Jessica Maloney  Technical Analyst, National Institute for Health and Care Excellence  Present for notes 57 to 69

Frances Nixon  Technical Adviser, National Institute for Health and Clinical Excellence  Present for notes 57 to 69

Ms Angela Stainthorpe  Research Associate, Liverpool Reviews and Implementation Group (LRiG)  Present for notes 1 to 17

Mr Tosin Lambe  Research Associate, Liverpool Reviews and Implementation Group (LRiG)  Present for notes 1 to 17

Mr Nigel Fleeman  Research Associate, Liverpool Reviews and Implementation Group (LRiG)  Present for notes 1 to 17

Dr James Larkin  Consultant Medical Oncologist, Royal Marsden NHS Foundation Trust, clinical expert nominated by BMS  Present for notes 6 to 15
Dr Philip Savage  Consultant Medical Oncologist, Brighton and Sussex University Hospitals, clinical expert nominated by Kidney Cancer UK  Present for notes 6 to 15 and for notes 20 to 28

Mrs Lucy Willingale  Patient information and support lead, Kidney Cancer UK, patient expert nominated by Kidney Cancer UK  Present for notes 6 to 15 and for notes 20 to 28

Professor Peter Clark  Chair of NHS England Chemotherapy Clinical Reference Group and National Clinical Lead for CDF  Present for notes 1 to 45

Dr Jonathan Shepherd  Principal Research Fellow, Southampton Health Technology Assessment Centre  Present for notes 20 to 30

Professor Joanne Lord  Director and Professorial Fellow, Southampton Health Technology Assessment Centre  Present for notes 20 to 30 and for notes 46 to 54

Mr Olu Onyimadu  Senior Research Assistant, Southampton Health Technology Assessment Centre  Present for notes 20 to 30

Dr Miriam Brazzelli  Senior Research Fellow, Aberdeen HTA Group  Present for notes 33 to 43

Dr Ewen Cummins  Health Economist, Aberdeen HTA Group  Present for notes 33 to 43

Professor Noel Clarke  Professor of Urological Oncology, The Christie and Salford Royal Hospitals, Manchester, clinical expert nominated by the British Association of Urological Surgeons  Present for notes 33 to 41

Professor Nicholas James  Professor of Clinical Oncology, University Hospitals Birmingham NHS Foundation Trust, clinical expert nominated by Janssen  Present for notes 33 to 41

Dr Julia Murray  Consultant Clinical Oncologist, The Royal Marsden NHS Foundation Trust, clinical expert nominated by the British Uro-Oncology Group  Present for notes 33 to 41

Ms Emma Craske  Specialist Nurse, Prostate Cancer UK, patient expert nominated by Prostate Cancer UK  Present for notes 33 to 41
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 nivolumab with ipilimumab for untreated metastatic renal cell carcinoma [ID1182], cabozantinib for untreated metastatic renal cell carcinoma [ID1208], abiraterone for treating newly diagnosed metastatic hormone-naive prostate cancer [ID945], dupilumab for treating moderate to severe atopic dermatitis after topical treatments [ID1048] and ocrelizumab for treating relapsing multiple sclerosis [ID937].

2. The Chair welcomed Dr Mona Johnson and Professor Sarah Wild to their first meeting as a member of the Appraisal Committee

3. The Chair informed the Committee of the non-public observers at this meeting: Peter Groves, Therese Casanova, Sarah Khan, Helen Barnett, Emily Crowe, Ross Dent, Melinda Goodall, Heidi Livingstone, Edgar Masanga and Irina Voicechovskaja.

4. Apologies were received from Mr Diar Fattah, Professor John Cairns, and Dr Sanjay Kinra.
Any other Business

5. The Committee were given an update on the progress of other appraisals previously seen by the Committee and an update on personnel changes within the NICE Technology Appraisals team.

Notes from the last meeting

6. The Committee approved the minutes of the meeting held on 6 March 2018.

Appraisal of nivolumab with ipilimumab for untreated metastatic renal cell carcinoma [ID1182]

Part 2 – Closed session

7. The Chair informed all attendees that this appraisal would be discussed in closed session because the drug has not yet received a positive opinion from the CHMP.

8. The Chair welcomed the invited experts: Ms Angela Stainthorpe, Mr Tosin Lambe, Mr Nigel Fleeman, Dr James Larkin, Dr Philip Savage, Mrs Lucy Willingale and Professor Peter Clark to the meeting and they introduced themselves to the Committee.

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

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

10.1. Dr Amanda Adler, Dr Sanjeev Patel, Mr Mark Chapman, Ms Susan Faulds, Dr Mark Glover, Mr Richard Hoddes, Dr Mona Johnson, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Stephen Smith, Mr William Turner, Professor Nicky Welton, Mr Nigel Westwood, Professor Sarah Wild and Dr Stuart Williams 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 nivolumab with ipilimumab for untreated metastatic renal cell carcinoma [ID1182].

10.2. Dr Nicholas Latimer declared before the meeting that he has received consultancy fees from Bristol-Myers Squibb in relation to nivolumab (though not in this indication).
10.2.1. It was agreed that Dr Latimer would not participate in this section of the meeting.

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

11.1. 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 nivolumab with ipilimumab for untreated metastatic renal cell carcinoma [ID1182].
12. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

12.1. Ms Angela Stainthorpe, Mr Tosin Lambe, Mr Nigel Fleeman, Mrs Lucy Willingale and Professor Peter Clark 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 nivolumab with ipilimumab for untreated metastatic renal cell carcinoma [ID1182].

12.2. Dr James Larkin declared a personal specific financial interest as he has received research funding and consultancy fees from Bristol-Myers Squibb.
12.2.1. It was agreed that this declaration would not prevent Dr Larkin from participating in this section of the meeting

12.3. Dr Philip Savage declared a personal specific financial interest as he has received speaker fees and travel expenses from the company and from comparator companies.
12.3.1. It was agreed that this declaration would not prevent Dr Savage from participating in this section of the meeting

13. The Chair introduced the lead team, Mr Diar Fattah, Mr Nigel Westwood and Dr Stuart Williams who gave presentations on the clinical effectiveness and cost effectiveness of nivolumab with ipilimumab for untreated metastatic renal cell carcinoma [ID1182].

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

15. 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

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

17. The Chair then thanked the Evidence Review Group representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

18. The Committee continued to discuss the clinical and cost effectiveness of nivolumab with ipilimumab for untreated metastatic renal cell carcinoma [ID1182].
18.1. The committee decision was based on consensus.

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

Appraisal of cabozantinib for untreated metastatic renal cell carcinoma [ID1208]
Part 1 – Open session

20. The Chair welcomed the invited experts: Dr Philip Savage, Mrs Lucy Willingale, Professor Peter Clark, Dr Jonathan Shepherd, Professor Joanne Lord and Mr Olu Onyimadu to the meeting and they introduced themselves to the Committee.

21. The Chair welcomed company representatives from Ipsen to the meeting.

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

22.1. Dr Amanda Adler, Dr Sanjeev Patel, Mr Mark Chapman, Ms Susan Faulds, Dr Mark Glover, Mr Richard Hoddes, Dr Mona Johnson, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Stephen Smith, Mr William Turner, Professor Nicky Welton, Mr Nigel Westwood, Professor Sarah Wild and Dr Stuart Williams 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 cabozantinib for untreated metastatic renal cell carcinoma [ID1208].

22.2. Dr Nicholas Latimer declared that he had received consultancy fees from Pfizer relating to other disease areas and was a member of Pfizer’s global modelling committee between January 2017 and December 2017. 22.2.1. It was agreed that as this declaration did not relate to a specific comparator product Dr Latimer could participate in this section of the meeting.

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

23.1. 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 cabozantinib for untreated metastatic renal cell carcinoma [ID1208].

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

24.1. Mrs Lucy Willingale, Professor Peter Clark, Dr Jonathan Shepherd, Professor Joanne Lord and Mr Olu Onyimadu 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 cabozantinib for untreated metastatic renal cell carcinoma [ID1208].

24.2. Dr Philip Savage declared a personal specific financial interest as he has received speaker fees and travel expenses from the company and from comparator companies. Dr Savage also holds a small number of shares in Ipsen (less than £5,000). 24.2.1. It was agreed that these declarations would not prevent Dr Savage from participating in this section of the meeting.
25. The Chair introduced the lead team, Professor Nicky Welton, Mr Nigel Westwood and Dr Stuart Williams who gave presentations on the clinical effectiveness and cost effectiveness of cabozantinib for untreated metastatic renal cell carcinoma [ID1208].

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

27. 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.

28. 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

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

30. The Chair then thanked the Evidence Review Group representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

31. The Committee continued to discuss the clinical and cost effectiveness of cabozantinib for untreated metastatic renal cell carcinoma [ID1208].

31.1. The committee decision was based on consensus.

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

Appraisal of abiraterone for treating newly diagnosed metastatic hormone-naive prostate cancer [ID945]

Part 1 – Open session

33. The Chair welcomed the invited experts: Professor Peter Clark, Professor Noel Clarke, Professor Nicholas James, Dr Julia Murray, Ms Emma Craske, Mr Brian Davies, Dr Miriam Brazzelli and Dr Ewen Cummins to the meeting and they introduced themselves to the Committee.

34. The Chair welcomed company representatives from Janssen to the meeting.

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

35.1. Dr Amanda Adler, Dr Sanjeev Patel, Mr Mark Chapman, Ms Susan Faulds, Dr Mark Glover, Mr Richard Hoddes, Dr Mona Johnson, Mr Christopher O’Regan, Dr Stephen Smith, Mr William Turner, Professor Nicky Welton, Mr Nigel Westwood, Professor Sarah Wild and Dr Stuart Williams all declared that they knew of no personal specific financial
Dr Nicholas Latimer declared that he had received a consultancy fee from Janssen for providing a half-day training course on survival analysis. He also declared that he had received a consultancy fee from Astra Zeneca for giving advice on survival modelling for durvalumab as a monotherapy among patients with stage IIIB–IV NSCLC. 35.2.1. It was agreed that as this declaration did not relate to the intervention product or to a specific comparator product Dr Latimer could participate in this section of the meeting.

35.3. Professor Stephen Palmer declared that he had received a consultancy fee from Takeda in connection with brigatinib for NSCLC. 35.3.1. Takeda make leuprorelin, an androgen deprivation therapy and the intervention (abiraterone) and comparators are all taken with androgen deprivation therapy so the use of androgen deprivation therapy remains the same regardless of the recommendation for abiraterone. It was therefore agreed that Professor Palmer could participate in this section of the meeting.

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

36.1. 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 abiraterone for treating newly diagnosed metastatic hormone-naive prostate cancer [ID945].

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

37.1. Professor Peter Clark, Dr Julia Murray, Ms Emma Craske, Mr Brian Davies, Dr Miriam Brazzelli and Dr Ewen Cummins 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 abiraterone for treating newly diagnosed metastatic hormone-naive prostate cancer [ID945].

37.2. Professor Noel Clarke declared a personal specific financial interest as he has received speaker fees, honoraria and travel expenses from Janssen and other pharmaceutical companies involved in this area. 37.2.1. It was agreed that this declaration would not prevent Professor Clarke from participating in this section of the meeting.

37.3. Professor Nicholas James declared a personal specific financial interest as he has received speaker, consultancy fees and travel expenses from Janssen and from Sanofi. Professor Clarke also stated that he is chief
investigator for the STAMPEDE trial and lead investigator for the recently reported abiraterone comparison.

37.3.1. It was agreed that this declaration would not prevent Professor James from participating in this section of the meeting.

38. The Chair introduced the lead team, Dr Nicholas Latimer, Mr William Turner and Mr Nigel Westwood who gave presentations on the clinical effectiveness and cost effectiveness of abiraterone for treating newly diagnosed metastatic hormone-naive prostate cancer [ID945].

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

40. 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.

41. 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

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

43. The Chair then thanked the Evidence Review Group representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

44. The Committee continued to discuss the clinical and cost effectiveness of abiraterone for treating newly diagnosed metastatic hormone-naive prostate cancer [ID945].

44.1. The committee decision was based on consensus.

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

Appraisal of dupilumab for treating moderate to severe atopic dermatitis after topical treatments [ID1048]

Part 1 – Open session

46. The Chair welcomed the invited experts: Dr Graham Scotland and Dr Rodolfo Hernandez to the meeting and they introduced themselves to the Committee.

47. The Chair welcomed company representatives from Sanofi to the meeting.

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

48.1. Dr Amanda Adler, Dr Sanjeev Patel, Mr Mark Chapman, Ms Susan Faulds, Dr Mark Glover, Mr Richard Hoddes, Dr Mona Johnson, Dr
Nicholas Latimer, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Stephen Smith, Mr William Turner, Professor Nicky Welton, Mr Nigel Westwood, Professor Sarah Wild and Dr Stuart Williams 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 dupilumab for treating moderate to severe atopic dermatitis after topical treatments [ID1048].

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

49.1. 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 dupilumab for treating moderate to severe atopic dermatitis after topical treatments [ID1048].

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

50.1. 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 dupilumab for treating moderate to severe atopic dermatitis after topical treatments [ID1048].

51. 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.

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

53. 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.

54. The Chair then thanked the experts, Evidence Review Group and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

55. The Committee continued to discuss the clinical and cost effectiveness of dupilumab for treating moderate to severe atopic dermatitis after topical treatments [ID1048].

55.1. The committee decision was based on consensus.
56. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of ocrelizumab for treating relapsing multiple sclerosis [ID937]

Part 1 – Open session

57. The Chair welcomed the invited experts: Professor Jo Lord and Dr Geoff Frampton to the meeting and they introduced themselves to the Committee.

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

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

59.1. Dr Amanda Adler, Dr Sanjeev Patel, Mr Mark Chapman, Ms Susan Faulds, Dr Mark Glover, Mr Richard Hoddes, Dr Mona Johnson, Dr Nicholas Latimer, Mr Christopher O’Regan, Professor Stephen Palmer, Dr Stephen Smith, Mr William Turner, Professor Nicky Welton, Mr Nigel Westwood, Professor Sarah Wild and Dr Stuart Williams 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 ocrelizumab for treating relapsing multiple sclerosis [ID937].

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

60.1. 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 ocrelizumab for treating relapsing multiple sclerosis [ID937].

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

61.1. 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 ocrelizumab for treating relapsing multiple sclerosis [ID937].

62. 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.

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

64. 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.

65. 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**

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

67. The Chair then thanked the Evidence Review Group representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

68. The Committee continued to discuss the clinical and cost effectiveness of ocrelizumab for treating relapsing multiple sclerosis [ID937].

68.1. The committee decision was based on consensus.

69. 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**

Wednesday 6 June 2018 at 10 Spring Gardens, London SW1A 2BU.