Technology Appraisal Committee Meeting (Committee B)

Minutes: Confirmed

Date and Time: Thursday 16 November 2017, 10am to 5pm

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

| Present: | 1. Dr Amanda Adler (Chair) | Present for all notes, Chair for notes 1 to 14 and notes 28 to 46 |
| 2. Dr Sanjeev Patel (Vice-Chair) | Present for all notes, Chair for notes 15 to 27 |
| 3. Dr Ray Armstrong | Present for all notes |
| 4. Professor John Cairns | Present for all notes |
| 5. Mr Mark Chapman | Present for all notes |
| 6. Ms Susan Faulds | Present for all notes |
| 7. Dr Sumeet Gupta | Present for all notes |
| 8. Mr Richard Hoddes | Present for all notes |
| 9. Dr Miriam McCarthy | Present for all notes |
| 10. Mr Christopher O'Regan | Present for notes 15 to 40 |
| 11. Professor Stephen Palmer | Present for all notes |
| 12. Dr Danielle Preedy | Present for all notes |
| 13. Dr Stephen Smith | Present for notes 1 to 27 |
| 14. Professor Ken Stein | Present for all notes |
| 15. Dr Nicky Welton | Present for all notes |
| 16. Mr Nigel Westwood | Present for all notes |
| 17. Dr Stuart Williams | Present for all notes |

In attendance:

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

- **Dr Elisabeth George**
  - 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

- **Basham Anjum**
  - Administrator, National Institute for Health and Care Excellence
  - Present for all notes
<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Affiliation</th>
<th>Notes Presented</th>
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<tbody>
<tr>
<td>Ahmed Elsada</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>1 to 14 and 41 to 46</td>
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<td>Jasdeep Hayre</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>15 to 46</td>
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<tr>
<td>Stuart Wood</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>1 to 14</td>
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<tr>
<td>Thomas Palmer</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>28 to 40</td>
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<tr>
<td>Dr Tristan Snowsill</td>
<td>Research Fellow, Peninsular Health Technology Assessment Group</td>
<td>1 to 12</td>
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<tr>
<td>Dr Huiqin Yang</td>
<td>Senior Research Fellow, Peninsular Health Technology Assessment Group</td>
<td>1 to 12</td>
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<tr>
<td>Professor Anne Thomas</td>
<td>Professor of Cancer Therapeutics at the University of Leicester - clinical expert - nominated by the NCRI-ACP-RCP-RCR</td>
<td>1 to 12</td>
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<tr>
<td>Professor Daniel Hochhauser</td>
<td>Professor of Medical Oncology and consultant medical oncologist - University College London Hospitals NHS Foundation Trust - clinical expert - nominated by Bowel Cancer UK</td>
<td>1 to 12</td>
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<tr>
<td>Professor Richard Wilson</td>
<td>Professor in Cancer Medicine Centre at the Cancer Research &amp; Cell Biology, Queen's University Belfast and Consultant Oncologist, Cancer Centre at the Belfast City Hospital - clinical expert - nominated by BMS</td>
<td>1 to 12</td>
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<tr>
<td>Mr Momenul Haque</td>
<td>Patient expert -</td>
<td>1 to 12</td>
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Ms Asha Kaur

Patient expert - nominated by Bowel Cancer UK

Present for notes 1 to 12

Mr Professor Peter Clark

Chair of NHS England Chemotherapy Clinical Reference Group and National Clinical Lead for CDF

Present for notes 1 to 14

Dr Xavier Armoiry

Senior Research Fellow, Warwick Evidence

Present for notes 15 to 24 and for notes 28 to 38

Ewen Cummins

Warwick Evidence

Present for notes 15 to 24

Dr Hema Mistry

Assistant Professor, Warwick Evidence

Present for notes 15 to 24

Professor Philipp Niemeyer

Specialist for orthopaedics and trauma surgery, OCM Gemeinschaftspraxis GbR, OCM Klinik GmbH, Munich – clinical expert nominated by Co.Don

Present for notes 15 to 24

Mr Peter Auguste

Research Fellow in Medical Statistics and Epidemiology / Health Economist, Warwick Evidence

Present for notes 28 to 38

Dr G.J. Melendez-Torres

Assistant Professor of HTA, Epidemiology and Evidence, Warwick Evidence

Present for notes 28 to 38

Non-public attendees:

Helen Barnett

Senior Medical Editor, NICE

Present for all notes

Emma Kent

Present for notes 1 to 27

Heidi Livingstone

Senior Public Involvement Advisor, NICE

Present for all notes

Dr Jeremy Rodrigues

NICE Fellow

Present for all notes

Dr Segun Bello

Peninsular Health Technology Assessment Group

Present for notes 1 to 14

Dr Elham Nikram

Peninsular Health Technology Assessment Group

Present for notes 1 to 14

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 nivolumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1136], autologous chondrocyte implantation with chondrosphere for treating articular cartilage defects [ID851], beta interferon and glatiramer acetate for treating multiple sclerosis (review of TA32) [ID809] and lenvatinib with everolimus for previously treated advanced renal cell carcinoma [ID1029].

2. The Chair informed the Committee of the non-public observers at this meeting: Helen Barnett, Emma Kent, Heidi Livingstone, Dr Jeremy Rodrigues, Dr Segun Bello and Dr Elham Nikram.

3. Apologies were received from Mr Diar Fattah, Dr Mark Glover and Dr Sanjay Kinra.

4. The Chair informed the Committee that this would be the last meeting for Dr Ray Armstrong and Professor Ken Stein and thanked them for their contributions to the Committee over the years.

Any other Business

5. The Committee were given an update on the expected timelines for other appraisals.

Appraisal of nivolumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1136]

Part 2 – Closed session

*this appraisal was discussed before the drug had been considered by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA)*

6. The Chair welcomed the invited experts: Dr Tristan Snowsill, Dr Huiqin Yang, Professor Peter Clark, Professor Anne Thomas, Professor Daniel Hochhauser, Professor Richard Wilson, Mr Momenul Haque and Ms Asha Kaur to the meeting and they introduced themselves to the Committee.

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

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

8.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Professor John Cairns, Mr Mark Chapman, Ms Susan Faulds, Dr Sumeet Gupta, Mr Richard Hoddes, Dr Miriam McCarthy, Professor Stephen Palmer, Dr Danielle Preedy, Dr Stephen Smith, Professor Ken Stein, Dr Nicky Welton, Mr Nigel Westwood 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 for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1136].

9. The Chair asked all NICE Staff to declare any relevant interests.
9.1. 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 for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1136].

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

10.1. Dr Tristan Snowsill, Dr Huiqin Yang, Professor Peter Clark, Professor Daniel Hochhauser, Mr Momenul Haque and Ms Asha Kaur 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 for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1136].

10.2. Professor Anne Thomas declared a personal non-specific financial interest as she has taken part in advisory boards for a number of pharmaceutical companies, including Bristol Myers-Squibb.  
10.2.1. It was agreed that this declaration would not prevent Professor Thomas from participating in this section of the meeting

10.3. Professor Richard Wilson declared a personal non-specific financial interest as he has taken part in advisory boards for a number of pharmaceutical companies, including Bristol Myers-Squibb.  
10.3.1. It was agreed that this declaration would not prevent Professor Wilson from participating in this section of the meeting

11. The Chair introduced the lead team, Dr Stuart Williams, Professor Stephen Palmer and Dr Danielle Preedy who gave presentations on the clinical effectiveness and cost effectiveness of nivolumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1136].

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

13. 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

14. The Committee continued to discuss the clinical and cost effectiveness of nivolumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1136].

14.1. The committee decision was based on consensus.

15. The Committee instructed the technical team to prepare the guidance document in line with their decisions.
Appraisal of autologous chondrocyte implantation with chondrosphere for treating articular cartilage defects [ID851]

Part 1 – Open session

16. The Committee approved the minutes of the meeting held on 18 October 2017.

17. The Chair welcomed the invited experts, Dr Xavier Armoiry, Ewen Cummins, Dr Hema Mistry and Professor Philipp Niemeyer to the meeting and they introduced themselves to the Committee.

18. The Chair welcomed company representatives from Co.don to the meeting.

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

19.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Professor John Cairns, Mr Mark Chapman, Ms Susan Faulds, Dr Sumeet Gupta, Mr Richard Hoddes, Dr Miriam McCarthy, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Danielle Preedy, Dr Stephen Smith, Professor Ken Stein, Dr Nicky Welton, Mr Nigel Westwood 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 autologous chondrocyte implantation with chondrosphere for treating articular cartilage defects [ID851].

20. The Chair asked all NICE Staff to declare any 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 autologous chondrocyte implantation with chondrosphere for treating articular cartilage defects [ID851].

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

21.1. Dr Xavier Armoiry, Ewen Cummins and Dr Hema Mistry 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 autologous chondrocyte implantation with chondrosphere for treating articular cartilage defects [ID851].

21.2. Professor Philipp Niemeyer declared a personal non specific financial interest as he has received honoraria for limited educational purpose from Co.don.

21.2.1. It was agreed that this declaration would not prevent Professor Niemeyer from participating in this section of the meeting.
22. The Chair introduced the lead team, Dr Ray Armstrong, Professor John Cairns and Mr Nigel Westwood who gave presentations on the clinical effectiveness and cost effectiveness of autologous chondrocyte implantation with chondrosphere for treating articular cartilage defects [ID851].

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

24. 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.

25. 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

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

27. The Committee continued to discuss the clinical and cost effectiveness of autologous chondrocyte implantation with chondrosphere for treating articular cartilage defects [ID851].

27.1. The committee decision was based on consensus.

28. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of beta interferon and glatiramer acetate for treating multiple sclerosis (review of TA32) [ID809]

Part 1 – Open session

29. The Chair welcomed the invited experts: Dr Xavier Armoiry, Mr Peter Auguste and Dr G.J. Melendez-Torres to the meeting and they introduced themselves to the Committee.

30. The Chair welcomed company representatives from Biogen, Merck, Novartis and Teva to the meeting.

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

31.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Professor John Cairns, Mr Mark Chapman, Ms Susan Faulds, Dr Sumeet Gupta, Mr Richard Hoddes, Dr Miriam McCarthy, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Danielle Preedy, Professor Ken Stein, Dr Nicky Welton, Mr Nigel Westwood 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
32. The Chair asked all NICE Staff to declare any relevant interests.

32.1. 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 beta interferon and glatiramer acetate for treating multiple sclerosis (review of TA32) [ID809].

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

33.1. Dr Xavier Armoiry, Mr Peter Auguste and Dr G.J. Melendez-Torres 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 beta interferon and glatiramer acetate for treating multiple sclerosis (review of TA32) [ID809].

34. The Chair introduced the key themes arising from the addendum prepared by the Assessment Group and the consultation responses to this addendum received from consultees, commentators and through the NICE website.

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

36. 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.

37. 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

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

39. The Assessment Group representatives left the meeting.

40. The Committee continued to discuss the clinical and cost effectiveness of beta interferon and glatiramer acetate for treating multiple sclerosis (review of TA32) [ID809].

40.1. The committee decision was based on consensus.
41. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of lenvatinib with everolimus for previously treated advanced renal cell carcinoma [ID1029]

Part 1 – closed section

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

    42.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Professor John Cairns, Mr Mark Chapman, Ms Susan Faulds, Dr Sumeet Gupta, Mr Richard Hoddes, Dr Miriam McCarthy, Professor Stephen Palmer, Dr Danielle Preedy, Professor Ken Stein, Dr Nicky Welton, Mr Nigel Westwood 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 lenvatinib with everolimus for previously treated advanced renal cell carcinoma [ID1029].

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

    43.1. 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 lenvatinib with everolimus for previously treated advanced renal cell carcinoma [ID1029].

44. The Chair introduced the additional information sent to NICE by the company.

45. The Committee continued to discuss the clinical and cost effectiveness of lenvatinib with everolimus for previously treated advanced renal cell carcinoma [ID1029].

    45.1. The committee decision was based on consensus.

46. The Committee instructed the technical team to prepare the Final Appraisal Determination in line with their decisions.

Date, time and venue of the next meeting

47. Thursday 4 January 2018 at 10am to 5pm, Prospero House, 241 Borough High Street, London SE1 1GA