Technology Appraisal Committee Meeting (Committee D)

Minutes: Confirmed

Date and Time: Thursday 26 October 2017, 10 – 16.30

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

1. Professor Gary McVeigh (Chair) Present for all notes
2. Dr Lindsay Smith (Vice Chair) Present for all notes
3. Dr Nabeel Alsindi Present for all notes
4. Professor David Bowen Present for all notes
5. Dr Matthew Bradley Present for all notes
6. Dr Ian Davidson Present for all notes
7. Professor Simon Dixon Present for all notes
8. Mrs Susan Dutton Present for all notes
9. Professor Rachel Elliott Present for all notes
10. Mrs Gillian Ells Present for all notes
11. Professor Paula Ghaneh Present for all notes
12. Dr Peter Hall Present for all notes
13. Dr Rebecca Harmston Present for all notes
14. Dr David Meads Present for all notes
15. Dr Malcolm Oswald Present for all notes
16. Mr William Turner Present for all notes

In attendance:

Maiwenn Ali ERG representative, Kleijnen Systematic Reviews Ltd Present for notes 1 to 12
Xavier Armoiry ERG representative, Warwick Evidence Present for notes 16 to 24, and 40 to 48
Peter Auguste ERG representative, Warwick Evidence Present for notes 16 to 24
Meindert Boysen Programme Director, National Institute for Health and Care Excellence Present for all notes
Lindsay Claxton ERG representative, Centre for Reviews and Dissemination and Centre for Health Economics – York Consultant Present for notes 28 to 36
Prof Gordon Cook Haematologist, Clinical Expert, nominated by UK Present for notes 40 to 48
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Present for notes</th>
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<tbody>
<tr>
<td>Sophie Cooper</td>
<td>MF Technical Analyst, National Institute for Health and Care Excellence</td>
<td>28 to 51</td>
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<tr>
<td>Professor Peter Clark</td>
<td>CDF Clinical lead ERG representative, Warwick Evidence</td>
<td>16 to 51</td>
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<tr>
<td>Ewen Cummins</td>
<td>ERG representative, Warwick Evidence</td>
<td>16 to 48</td>
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<tr>
<td>Professor Geoff Dusheiko</td>
<td>Emeritus Professor Medicine, Clinical Expert, nominated by AbbVie Patient Expert, nominated by Myeloma UK</td>
<td>1 to 12</td>
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<td>John Ellwood</td>
<td>Patient Expert, nominated by Myeloma UK</td>
<td>40 to 48</td>
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<tr>
<td>Daniel Gallacher</td>
<td>ERG representative, Warwick Evidence</td>
<td>16 to 24</td>
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<tr>
<td>Charles Gore</td>
<td>Patient Expert, nominated by the Hepatitis C Trust</td>
<td>1 to 12</td>
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<td>Christian Griffiths</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>16 to 39</td>
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<tr>
<td>Dr Matthew Hatton</td>
<td>Consultant Clinical Oncologist, Clinical Expert, nominated by NCRI-ACP-RCP-RCR</td>
<td>28 to 36</td>
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<tr>
<td>Suzy Heafield</td>
<td>Commercial Pharmacy Lead, NHS England ERG representative, Centre for Reviews and Dissemination and Centre for Health Economics – York Consultant Hepatologist, Clinical Expert, nominated by British Society of Gastronenterology</td>
<td>1 to 12</td>
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<tr>
<td>Rob Hodgson</td>
<td>Patient Expert, nominated by Myeloma UK</td>
<td>40 to 48</td>
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<tr>
<td>Dr Syed Hussaini</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>1 to 15</td>
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<td>Victoria Kelly</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>1 to 15</td>
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<tr>
<td>Helen Knight</td>
<td>Associate Director, National Institute for Health and Care Excellence</td>
<td>all notes</td>
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<tr>
<td>Shelagh McKinlay</td>
<td>Patient Expert, nominated by Myeloma UK</td>
<td>40 to 48</td>
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<tr>
<td>Kate Moore</td>
<td>Project Manager, National Institute for</td>
<td>all notes</td>
</tr>
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Health and Care Excellence

Dr Karthik Ramasamy Consultant Haematologist, Clinical Expert, nominated by UK MF Present for notes 40 to 48

Alex Sexton Administrator, National Institute for Health and Care Excellence Present for all notes

Raisa Sidhu Technical Adviser, National Institute for Health and Clinical Excellence Present for notes 40 to 51

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

Dr Yvonne Summers Consultant Medical Oncologist, Clinical Expert, nominated by Novartis Present for notes 28 to 36

Nwamaka Umeweni Technical Adviser, National Institute for Health and Clinical Excellence Present for notes 1 to 15

Nerys Woolacott ERG representative, Centre for Reviews and Dissemination and Centre for Health Economics – York Present for notes 28 to 36

Non-public observers:

Sohaib Ashraf Health Economist, NICE Present for all notes
Shana Butterworth Human Resources, NICE Present for notes 1 to 27
Ann Greenwood Senior Editor, NICE Present for all notes
Henry Edwards Technical Adviser, NICE Present for notes 40 to 51
Linda Landells Associate Director, NICE Present for notes 40 to 51
Maroulla Whitely Business Analyst, NICE 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 glecaprevir with pibrentasvir for treating chronic
hepatitis C, pembrolizumab for previously treated advanced or metastatic urothelial cancer, ceritinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer, and ixazomib citrate for treating relapsed or refractory multiple myeloma.

2. Apologies were received from Dr Aomesh Bhatt, Sumithra Maheswaran and Professor Oluwafemi Oyebode

Any other Business

3. None.

Appraisal of glecaprevir with pibrentasvir for treating chronic hepatitis C [ID1085]

Part 1 – Open session

4. The Vice Chair welcomed the invited experts: Maiwenn Al, Professor Geoff Dusheiko, Charles Gore, Suzy Heafield and Dr Syed Hussaini to the meeting and they introduced themselves to the Committee.

5. The Vice Chair welcomed company representatives from AbbVie Ltd to the meeting.

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

Dr Nabee Al, Professor David Bowen, Dr Matthew Bradley, Dr Ian Davidson, Mrs Susan Dutton, Professor Rachel Elliott, Mrs Gillian Ells, Professor Paula Ghanem, Dr Peter Hall, Dr Rebecca Harmston, Professor Gary McVeigh, Dr David Meads, Dr Malcolm Oswald, Dr Lindsay Smith and Mr William Turner 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 glecaprevir with pibrentasvir for treating chronic hepatitis C.

6.1. Professor Simon Dixon declared a non-personal non-specific financial interest as he is Director of a Health Economics Unit that has undertaken research for a comparator company on unrelated topics; he was not directly involved in the work and the university received payment for the work.

6.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.

7. The Vice 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 glecaprevir with pibrentasvir for treating chronic hepatitis C.

8. The Vice Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
8.1. Maiwenn Al, Suzy Heafield and Dr Syed Hussaini 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 glecaprevir with pibrentasvir for treating chronic hepatitis C.

8.2. Charles Gore declared a specific non-person financial interest as the Hepatitis C Trust has received funding from the manufacturer. 8.2.1. It was agreed that this declaration would not prevent Charles Gore from participating in this section of the meeting.

8.3. Professor Geoff Dusheiko declared a specific non-person financial interest as he has acted as an adviser for the manufacturer and comparator companies. 8.3.1. It was agreed that this declaration would not prevent Professor Geoff Dusheiko from participating in this section of the meeting.

9. The Vice Chair introduced the lead team, Professor Simon Dixon, Mrs Gillian Ells and Dr Rebecca Harmston who gave presentations on the clinical effectiveness and cost effectiveness of glecaprevir with pibrentasvir for treating chronic hepatitis C.

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

11. The Vice 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 Vice 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 glecaprevir with pibrentasvir for treating chronic hepatitis C.

14.1. The committee decision was based on consensus.

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

**Appraisal of pembrolizumab for previously treated advanced or metastatic urothelial cancer [ID1019]**

**Part 1 – Open session**
16. The Chair welcomed the invited experts Xavier Armoiry, Peter Auguste, Professor Peter Clark and Daniel Gallacher to the meeting and they introduced themselves to the Committee.

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

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

18.1. Dr Nabeel Alsindi, Professor David Bowen, Dr Matthew Bradley, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Mrs Gillian Ells, Professor Rachel Elliott, Professor Paula Ghaneh, Dr Peter Hall, Dr Rebecca Harmston, Professor Gary McVeigh, Dr David Meads, Dr Malcolm Oswald, Dr Lindsay Smith, Mr William Turner 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 pembrolizumab for previously treated advanced or metastatic urothelial cancer.

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 pembrolizumab for previously treated advanced or metastatic urothelial cancer.

20. The Chair asked all other invited guests (assessment group/ERG and experts) 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 pembrolizumab for previously treated advanced or metastatic urothelial cancer.

21. 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.

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 pembrolizumab for previously treated advanced or metastatic urothelial cancer

26.1. A vote was taken. The options were:

   Option 1: pembrolizumab could be suitable for use in the Cancer Drugs Fund

   Option 2: pembrolizumab is not suitable to be recommended for use in the Cancer Drugs Fund

   The Committee voted for Option 2.

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

**Appraisal of ceritinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer [ID1117]**

**Part 1 – Open session**

28. The Chair welcomed the invited experts: Professor Peter Clark, Lindsay Claxton, Dr Matthew Hatton, Rob Hodgson, Dr Yvonne Summers, Nerys Woolacott, to the meeting and they introduced themselves to the Committee.

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

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

30.1. Dr Nabeel Alsindi, Professor David Bowen, Dr Matthew Bradley, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Peter Hall, Dr Rebecca Harmston, Professor Gary McVeigh, Dr David Meads, Dr Malcolm Oswald, Dr Lindsay Smith, Mr William Turner 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 ceritinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer.

30.2. Professor Rachel Elliott declared a non-specific personal financial interest as she had received a personal honorarium from a comparator company for attending an advisory board for an unrelated topic in the past twelve months.
30.2.1 It was agreed that this declaration would not prevent Professor Rachel Elliott from participating in this section of the meeting.

30.3. Professor Simon Dixon declared a non-specific personal financial interest as he is Director of a Health Economics Unit that has undertaken research for Takeda and a comparator company on unrelated topics; he was not directly involved in the work and the university received payment for the work.
30.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.

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 ceritinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer.

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

32.1. Lindsay Claxton, Dr Matthew Hatton, Rob Hodgson and Nerys Woolacott, 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 ceritinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer.

32.2. Dr Yvonne Summers declared a personal non-specific financial interest as she had participated in advisory boards for comparator companies in the past twelve months.
32.2.1. It was agreed that this declaration would not prevent Dr Yvonne Summers from participating in this section of the meeting.

33. The Chair introduced the lead team, Mrs Susan Dutton, Professor Paula Ghaneh and Dr Rebecca Harmston who gave presentations on the clinical effectiveness and cost effectiveness of ceritinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer.

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

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

38. The Committee continued to discuss the clinical and cost effectiveness of ceritinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer.

38.1. The committee decision was based on consensus.

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

Appraisal of ixazomib citrate for treating relapsed or refractory multiple myeloma [ID807]

Part 1 – Open session

40. The Chair welcomed the invited experts: Xavier Armoiry, Professor Gordon Cook, Ewen Cummins, John Ellwood, Shelagh McKinlay, Dr Karthik Ramasamy to the meeting and they introduced themselves to the Committee.

41. The Chair welcomed company representatives from Takeda to the meeting.

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

42.1. Dr Nabeel Alsindi, Professor David Bowen, Dr Matthew Bradley, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Professor Rachel Elliott, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Peter Hall, Dr Rebecca Harmston, Professor Gary McVeigh, Dr Malcolm Oswald, Dr Lindsay Smith, Mr William Turner 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 ixazomib citrate for treating relapsed or refractory multiple myeloma.

42.2. Professor Simon Dixon declared a non-specific personal financial interest as he is Director of a Health Economics Unit that has undertaken research for the company and a comparator company on unrelated topics; he was not directly involved in the work and the university received payment for the work.

42.2.1. It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.

42.3. Dr David Meads declared a specific non-personal financial interest as he is the lead economist on two on-going studies which include one of the treatments (ixazomib). For both studies his university has received funding from the company; he had not received any personal funding.

42.3.1. It was agreed that this declaration would prevent Dr David Meads from participating in this section of the meeting.
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 ixazomib citrate for treating relapsed or refractory multiple myeloma.

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

44.1. Xavier Armoiry, Ewen Cummins, and Shelagh McKinlay 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 ixazomib citrate for treating relapsed or refractory multiple myeloma.

44.2. Professor Gordon Cook declared a non-specific personal financial interest as he had received consultancy fees and support for meeting attendances from the company.

44.2.1. It was agreed that this declaration would not prevent Professor Gordon Cook from participating in this section of the meeting.

44.3. John Ellwood declared a specific personal financial interest as he had received an honorarium from the company for making a film for their employees describing his patient experience.

44.3.1. It was agreed that this declaration would not prevent John Ellwood from participating in this section of the meeting.

44.4. Dr Karthik Ramasamy declared a non-specific personal financial interest as he had received speaker fees and support for meeting attendances from the company.

44.4.1. It was agreed that this declaration would not prevent Dr Karthik Ramasamy from participating in this section of the meeting.

45. 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.

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

47. 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.
48. 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**

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

50. The Committee continued to discuss the clinical and cost effectiveness of ixazomib citrate for treating relapsed or refractory multiple myeloma.

50.1. The committee decision was based on consensus.

51. 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**

52. Thursday 23 November 2017 from 10.00 am to 17.00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.