Technology Appraisal Committee Meeting (Committee D)

Minutes: Confirmed

Date and Time: Wednesday 29 March 2017, 10.00 – 16.00

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

Present:
1. Professor Gary McVeigh (Chair) Present for all notes
2. Dr Lindsay Smith (Vice Chair) Present for all notes
3. Dr Aomesh Bhatt 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 notes 1 to 29
7. Professor Simon Dixon Present for all notes
8. Professor Rachel Elliott Present for all notes
9. Professor Paula Ghaneh Present for all notes
10. Dr Rebecca Harmston Present for all notes
11. Dr Peter Hall Present for all notes
12. Sumithra Maheswaran Present for all notes
13. Dr David Meads Present for all notes
14. Mr Malcolm Oswald Present for all notes
15. Professor Femi Oyebode Present for all notes
16. Mr William Turner Present for all notes

In attendance:

Dr Xavier Armoiry Evidence Review Group representative, Warwick Evidence Present for notes 1 to 13

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

Dr Paul Cane Consultant Histopathologist, clinical expert, nominated by the Royal College of Pathologists Present for notes 17 to 25

Professor Aileen Clark Evidence Review Group representative, Warwick Evidence Present for notes 1 to 13

Professor Peter Clark CDF Clinical Lead, NHS England Present for notes 1 to 29
<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Affiliation</th>
<th>Notes Present:</th>
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<tbody>
<tr>
<td>Sophie Cooper</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>1 to 16</td>
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<tr>
<td>Dr Ewen Cummins</td>
<td>Evidence Review Group representative, Warwick Evidence</td>
<td>1 to 13</td>
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<tr>
<td>Chris Griffiths</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>30 to 41</td>
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<tr>
<td>Marcela Haasova</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>17 to 29</td>
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<tr>
<td>Dr Tracey Jones-Hughes</td>
<td>Assessment Group representative, PenTAG</td>
<td>30 to 38</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>David Lobb</td>
<td>Patient expert, nominated by Myeloma UK</td>
<td>1 to 13</td>
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<tr>
<td>Fay McCracken</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>17 to 29</td>
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<tr>
<td>Shelagh McKinlay</td>
<td>Patient expert, nominated by Myeloma UK</td>
<td>1 to 13</td>
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<tr>
<td>Kate Moore</td>
<td>Project Manager, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<tr>
<td>Keith Pennington</td>
<td>Patient expert, nominated by the British Kidney Patient Association</td>
<td>30 to 38</td>
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<tr>
<td>Helen Powell</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>30 to 41</td>
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<tr>
<td>Name</td>
<td>Role and Expertise</td>
<td>Present for notes</td>
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<tr>
<td>Dr Karthik Ramasamy</td>
<td>Consultant haematologist, clinical expert, nominated by UK Myeloma Forum</td>
<td>1 to 13</td>
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<tr>
<td>Keith Rigg</td>
<td>Chair, Rental Transplant Clinical Reference Group, NHS England</td>
<td>30 to 38</td>
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<tr>
<td>Alex Sexton</td>
<td>Administrator, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<tr>
<td>Raisu Sidhu</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>1 to 16</td>
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<tr>
<td>Dr Tristan Snowshill</td>
<td>Assessment Group representative, PenTAG</td>
<td>30 to 38</td>
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<tr>
<td>Dr Nicholas Torpey</td>
<td>Consultant nephrologist, clinical expert, nominated by the British Kidney Association</td>
<td>30 to 38</td>
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<tr>
<td>Ian Watson</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>30 to 41</td>
</tr>
<tr>
<td>Professor Nicholas Webb</td>
<td>Consultant paediatric nephrologist, clinical expert, nominated by Astellas Pharma Ltd</td>
<td>30 to 38</td>
</tr>
<tr>
<td>Professor Kwee Yong</td>
<td>Professor of Haematology, clinical expert, nominated by UK Myeloma Forum</td>
<td>1 to 13</td>
</tr>
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</table>

**Non-public observers:**

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<thead>
<tr>
<th>Name</th>
<th>Role and Expertise</th>
<th>Present for notes</th>
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</thead>
<tbody>
<tr>
<td>Karyo Angeloudis</td>
<td>Analyst, PASUL National Institute for Health and Care Excellence</td>
<td>17 to 41</td>
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<tr>
<td>John Borrill</td>
<td>Technical Adviser, Scientific Advice, National Institute for Health and Care Excellence</td>
<td>17 to 29</td>
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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 ixazomib citrate for treating relapsed or refractory multiple myeloma, pembrolizumab for untreated PD-L1 positive metastatic non-small-cell lung cancer, immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99), and Immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).

2. The Chair welcomed Dr Rebecca Harmston, Dr Peter Hall, and Mr William Turner as new members of the Appraisal Committee.

3. Apologies were received from Susan Dutton, Gillian Ells and Dr Paula Parvulescu.
Any other Business

4. None

Appraisal of ixazomib citrate for treating relapsed or refractory multiple myeloma

Part 1 – Open session

5. The Chair welcomed the invited experts, Dr Xavier Armoiry, Professor Aileen Clark, Professor Peter Clark, Dr Ewen Cummins, David Lobb, Shelagh McKinlay, Dr Karthik Ramasamy and Professor Kwee Yong, to the meeting and they introduced themselves to the Committee.

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

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

7.1. Dr Aomesh Bhatt, Professor David Bowen, Dr Matthew Bradley, Dr Ian Davidson, Professor Rachel Elliott, Professor Paula Ghaneh, Dr Rebecca Harmston, Dr Peter Hall, Sumithra Maheswaran, Professor Gary McVeigh, Malcolm Oswald, Professor Femi Oyebode, and Dr Lindsay Smith 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.

7.2. Professor Simon Dixon declared a non-specific non-personal financial interest as he is the Director of a Health Economics Unit that has undertaken work for comparator companies. 7.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.

7.3. Dr David Meads declared a specific non-personal financial interest as his University has received funding from the company for on-going research. 7.3.1 It was agreed that this declaration would prevent Dr David Meads from participating in this section of the meeting.

7.4. Williams Turner declared a non-specific personal financial interest as his wife holds shares in Worldwide Healthcare Trust PLC. 7.4.1 It was agreed that this declaration would prevent William Turner from participating in this section of the meeting.

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

8.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of ixazomib citrate for treating relapsed or refractory multiple myeloma.
9. The Chair asked all other invited guests to declare their relevant interests.

9.1. Dr Xavier Armoiry, Professor Aileen Clark, Dr Ewen Cummins, Shelagh McKinlay, and David Lobb 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.

9.2. Dr Karthik Ramasamy declared a non-specific personal non-financial interest as he had participated in and been a speaker at symposia organised by the company.

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

9.3. Professor Kwee Yong declared a non-specific personal financial interest as she had received funding for attending advisory boards from the company and comparator companies.

9.3.1. It was agreed that this declaration would not prevent Professor Kwee Yong from participating in this section of the meeting.

10. The Chair introduced the lead team, Professor David Bowen, Professor Paula Ghaneh, and Malcolm Oswald, who gave presentations on the clinical effectiveness and cost effectiveness of ixazomib citrate for treating relapsed or refractory multiple myeloma.

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

12. 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.

13. 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

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

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

15.1. The committee decision was based on consensus.

16. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.
Appraisal of pembrolizumab for untreated PD-L1 positive metastatic non-small-cell lung cancer

Part 1 – Open session

17. The Vice Chair welcomed the invited experts, Dr Paul Cane and Professor Peter Clark, and they introduced themselves to the Committee.

18. The Vice Chair welcomed company representatives from Merck Sharp & Dohme UK Ltd to the meeting.

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

19.1. Dr Aomesh Bhatt, Professor David Bowen, Dr Matthew Bradley, Dr Ian Davidson, Professor Simon Dixon, Professor Rachel Elliott, Professor Paula Ghaneh, Dr Rebecca Harmston, Dr Peter Hall, Sumithra Maheswaran, Professor Gary McVeigh, Dr David Meads, Mr Malcolm Oswald, Professor Femi Oyebode, and Dr Lindsay Smith 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 untreated PD-L1 positive metastatic non-small-cell lung cancer.

19.2. Williams Turner declared a non-specific personal financial interest as his wife holds shares in Worldwide Healthcare Trust PLC.

19.2.1 It was agreed that this declaration would prevent William Turner from participating in this section of the meeting.

20. The Vice 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 for untreated PD-L1 positive metastatic non-small-cell lung cancer.

21. The Vice Chair asked all other invited guests to declare their relevant interests.

21.1. Professor Peter Clark declared that he 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 untreated PD-L1 positive metastatic non-small-cell lung cancer.

21.2. Dr Paul Cane declared a non-specific personal financial interest as he had received conference sponsorship from the company.

22.2.1 It was agreed that this declaration would not prevent Dr Paul Cane from participating in this section of the meeting.
22. The Vice 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.

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 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 pembrolizumab for untreated PD-L1 positive metastatic non-small-cell lung cancer.

28. A vote was taken. The options were:
   Option 1: Yes – Recommend
   Option 2: No – Do not recommend

   The Committee voted for Option 2

29. 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 immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85) and appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99)

Part 1 – Open session

30. The Chair welcomed the invited experts, Dr Tracey Jones-Hughes, Keith Pennington, Dr Tristan Snowhill, Dr Nicholas Torpey, and Professor Nicholas Webb, to the meeting and they introduced themselves to the Committee.

31. The Chair welcomed company representatives from Astellas, Chiesi, Novartis, Sanofi Genzyme, Sandoz and Teva to the meeting.

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

   32.1. Dr Aomesh Bhatt, Professor David Bowen, Dr Matthew Bradley, Dr Ian Davidson, Professor Rachel Elliott, Professor Paula Ghaneh, Dr Rebecca Harmston, Sumithra Maheswaran, Professor Gary McVeigh, Dr David Meads, Mr Malcolm Oswald, Professor Femi Oyebode, and Dr Lindsay
Smith 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 Appraisal of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85) and appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).

32.2. Professor Simon Dixon declared a non-specific personal financial interest and a non-specific non-personal financial interest as he has undertaken paid work for one of the companies on an unrelated topic and is the Director of a Health Economics Unit that has undertaken work on unrelated topics for comparator companies.

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

32.3. Dr Peter Hall declared a non-specific non-personal financial interest as his University department had received advisory board fees from a comparator company for unrelated topics.

32.3.1 It was agreed that this declaration would not prevent Dr Peter Hall from participating in this section of the meeting.

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

33.1. 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 immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85) and appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).

34. The Chair asked all other invited guests to declare their relevant interests.

34.1. Dr Tracey Jones-Hill, Keith Pennington, Keith Rigg, Dr Tristan Snowshill, and Dr Nicholas Torpey 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 immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85) and appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).

34.2. Professor Nicholas Webb declared a personal non-specific financial interest as he has participated in an advisory board and received consultancy fees from one of the companies.

34.2.1 It was agreed that this declaration would not prevent Professor Nicholas Webb from participating in this section of the meeting.
35. The Chair introduced the background to the appraisals, the key themes arising from the appeals against the FAD and from consideration of the appeal panel’s conclusions.

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

37. 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.

38. 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

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

40. The Committee continued to discuss the clinical and cost effectiveness of immunosuppressive therapy for kidney transplantation in adults and immunosuppressive therapy for kidney transplantation in children and adolescents.

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

Date, time and venue of the next meeting

42. Wednesday 26 April 2017, from 10am -5pm at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.