

Technology Appraisal Committee Meeting (Committee D)

Minutes: **Confirmed**

Date and Time: **Tuesday 7 July 2015, 10 am to 5.30pm**

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

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| Present: | 1. Professor Gary McVeigh (Chair) 2. Dr Lindsay Smith (Vice Chair) 3. Dr Andrew Black 4. Dr David Bowen 5. Dr Matthew Bradley 6. Dr Ian Davidson 7. Professor Simon Dixon 8. Mrs Susan Dutton 9. Mrs Gillian Ells 10. Professor Carol Haigh 11. Professor John Henderson 12. Dr Tim Kinnaird 13. Dr Warren Linley 14. Dr Malcolm Oswald 15. Prof Oluwafemi Oyebode 16. Dr Mohit Sharma 17. Dr Murray Smith | Present for all notes Present for notes all notes |
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In attendance:

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| Rob Anderson | Peninsula Technology Assessment Group (PenTAG) | Present for notes 5 to 14 and 18 to 27 |
| Michael Breswick | Patient expert British Kidney Patient Association | Present for notes 18 to 27 |
| Meindert Boysen | Programme Director, National Institute for Health and Care Excellence | Present for all notes |
| Chris Chesters | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 31 to 43 |
| Jacob Clarke | Patient expert nominated by Kidney Research UK | Present for notes 5 to 14 |
| Danielle Conroy | Administrator, National Institute for Health and | Present for all notes |

| Care Excellence | | |
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| Dr Sally Doss | Technical Adviser, National Institute for Health and Clinical Excellence | Present for notes 1 to 30 |
| Simone Goren | Patient expert nominated by the Polycystic Kidney Disease Charity Peninsula Technology Assessment Group (PenTAG) | Present for notes 31 to 40 |
| Marcela Haasova | | Present for notes 5 to 14 and 18 to 27 |
| Paul Harden | Clinical expert nominated by the Royal College of Physicians | Present for notes 18 to 27 (by teleconference) |
| Sarah-Louise Harwood | Patient expert nominated by Kidney Research UK | Present for notes 18 to 27 |
| Tracey Jones-Hughes | Peninsula Technology Assessment Group (PenTAG) | Present for notes 5 to 14 and 18 to 27 |
| Helen Knight | Associate Director, National Institute for Health and Care Excellence | Present for all notes |
| Dr Rosie Lovett | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 18 to 30 |
| Fay McCracken | Technical Adviser, National Institute for Health and Clinical Excellence | Present for notes 31 to 43 |
| David Milford | Clinical expert nominated by the British Association of Paediatric Nephrology | Present for notes 18 to 27 |
| Kate Moore | Project Manager, National Institute for Health and Care Excellence | Present for all notes |
| Ruben Mujica-Mota | Peninsula Technology Assessment Group (PenTAG) | Present for notes 5 to 14 and 18 to 27 |
| Keith Pennington | Patient expert nominated by British Kidney Patient Association | Present for notes 5 to 14 |
| Bram Ramaekers | Kleijnen Systematic Reviews Ltd | Present for notes 31 to 40 |
| John Sayer | Clinical expert nominated by the Polycystic Kidney Disease Charity | Present for notes 31 to 40 |
| Tristan Snowsill | Peninsula Technology Assessment Group | Present for notes 5 to 14 and 18 to 27 |

(PenTAG)

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| Robert Wolff | Kleijnen Systematic Reviews Ltd | Present for notes 31 to 40 |
| Christopher Watson | Clinical expert nominated by Bristol-Myers Squibb | Present for notes 5 to 14 |
| Ian Watson | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 1 to 17 |
| Theresa Williams | Patient expert nominated by the Polycystic Kidney Disease Charity | Present for notes 31 to 40 |
| Colin Wilson | Clinical expert nominated by Cochrane Renal Group | Present for notes 5 to 14 |

Non-public observers:

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| Bethan Dorsett | Digital Editor, National Institute for Health and Clinical Excellence | Present for notes 1 to 30 |
| Rob Hodgson | Centre for Reviews and Dissemination University of York | Present for notes 1 to 43 |

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 immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85), immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99) and tolvaptan for treating autosomal dominant polycystic kidney disease.
2. The Chair informed the Committee of the non-public observers at this meeting: Bethan Dorset and Rob Hodgson
3. Apologies were received from Dr Aomesh Bhatt, Dr Ian Campbell, Mrs Tracey Cole, Dr Alexander Dyker, Professor Paula Ghaneh and Dr Susan Griffin

Any other Business

4. The Programme Director, Meindert Boysen updated the committee members on the progress with the appraisals of Ledipasvir-sofosbuvir for treating chronic hepatitis C [ID742], Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C [ID731] and Daclatasvir for treating chronic hepatitis C [ID766].

Appraisal of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85)

Part 1 – Open session

5. The Chair welcomed the invited experts: Rob Anderson, Jacob Clarke, Marcela Haasova, Tracey Jones-Hughes, Ruben Mujica-Mota, Keith Pennington, Tristan Snowsill, Colin Wilson and Christopher Watson to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Astellas, Bristol-Myers Squibb, Novartis, Sandoz, Sanofi and Teva to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
 - 7.1. Dr Andrew Black, Dr David Bowden, Dr Matthew Bradley, Dr Ian Davidson, Mrs Susan Dutton, Mrs Gillian Ells, Professor Carol Haigh, Dr Tim Kinnaird, Mr Warren Linley, Professor Gary McVeigh (Chair), Dr Malcolm Oswald, Professor Femi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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).
 - 7.2. Professor Simon Dixon declared a non-personal non-specific pecuniary interest as part of the team that he is Director of had undertaken research for two of the companies on unrelated topics.
 - 9.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.
 - 7.3. Professor John Henderson declared a non-personal non-specific pecuniary interest as the institute that he works for had received funding from one of the companies involved in the appraisal. He did not receive personal remuneration from this funding.
 - 9.3.1 It was agreed that this declaration would prevent Professor John Henderson 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 pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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).
9. The Chair asked all other invited guests to declare their relevant interests.
 - 9.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary

- interest, non-personal non-specific pecuniary 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).
10. The Chair introduced the lead team, Professor David Bowen and Dr Warren Linley who gave presentations on the clinical effectiveness and cost effectiveness of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).
 11. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85) on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
 - 11.1. The nature of immunosuppressive therapies for kidney transplantation in adults, and current clinical practice in this area
 - 11.2. The Assessment Group's systematic review of clinical effectiveness and evidence presented by the companies
 - 11.3. Economic models presented by the Assessment Group and 3 companies
 - 11.4. The overall clinical and cost effectiveness of immunosuppressive therapies for kidney transplantation in adults
 12. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
 13. 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.
 14. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

15. Discussion on confidential information continued. This information was supplied by one of the companies.
16. The Committee continued to discuss the clinical and cost effectiveness of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).
17. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99)

Part 1 – Open session

18. The Chair welcomed the invited experts: Rob Anderson, Michael Breswick, Marcela Haasova, Paul Harden, Sarah-Louise Harwood, Tracey Jones-Hughes, David Milford, Ruben Mujica-Mota and Tristan Snowsill to the meeting and they introduced themselves to the Committee.
19. The Chair welcomed company representatives from Astellas, Novartis and Sanofi to the meeting.
20. The Chair asked all Committee members to declare any relevant interests
 - 20.1. Dr Andrew Black, Dr David Bowden, Dr Matthew Bradley, Dr Ian Davidson, Mrs Susan Dutton, Mrs Gillian Ells, Professor Carol Haigh, Dr Tim Kinnaird, Mr Warren Linley, Professor Gary McVeigh (Chair), Dr Malcolm Oswald, Professor Femi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 children and adolescents* (review of technology appraisal guidance 99).
 - 20.2. Professor Simon Dixon declared a non-personal non-specific pecuniary interest as part of the team that he is Director of had undertaken research for two of the companies on unrelated topics.
 - 9.2.1. It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.
 - 20.3. Professor John Henderson declared a non-personal non-specific pecuniary interest as the institute that he works for had received funding from one of the companies involved in the appraisal. He did not receive personal remuneration from this funding.
 - 9.3.1. It was agreed that this declaration would prevent Professor John Henderson from participating in this section of the meeting.
21. The Chair asked all NICE Staff to declare any relevant interests.
 - 21.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 children and adolescents* (review of technology appraisal guidance 99).
22. The Chair asked all other invited guests to declare their relevant interests.
 - 22.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 children and adolescents* (review of technology appraisal guidance 99).

23. The Chair introduced the lead team, Dr Andrew Black and Professor John Henderson who gave presentations on the clinical effectiveness and cost effectiveness of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
24. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99) on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
 - 24.1. The aspects of immunosuppression that are especially important for children and adolescents, including side effects and adherence.
 - 24.2. The Assessment Group's systematic review of the clinical evidence.
 - 24.3. The effect of different dosing regimens on adherence.
 - 24.4. The assessments of cost effectiveness, including the model from the Assessment Group and the model from Astellas Pharma
25. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
26. 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.
27. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

28. Discussion on confidential information continued. This information was supplied by one of the companies.
29. The Committee continued to discuss the clinical and cost effectiveness of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
30. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of tolvaptan for treating autosomal dominant polycystic kidney disease

Part 1 – Open session

31. The Chair welcomed the invited experts: Simone Goren, Bram Ramaekers, John Sayer, Theresa Williams and Robert Wolff to the meeting and they introduced themselves to the Committee.
32. The Chair welcomed company representatives from Otsuka to the meeting.

33. The Chair asked all Committee members to declare any relevant interests
- 33.1. Dr Andrew Black, Dr David Bowden, Dr Matthew Bradley, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Mrs Gillian Ells, Professor Carol Haigh, Professor John Henderson, Dr Tim Kinnaird, Mr Warren Linley, Professor Gary McVeigh (Chair), Dr Malcolm Oswald, Professor Femi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 tolvaptan for treating autosomal dominant polycystic kidney disease.
34. The Chair asked all NICE Staff to declare any relevant interests.
- 34.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 tolvaptan for treating autosomal dominant polycystic kidney disease.
35. The Chair asked all other invited guests to declare their relevant interests.
- 35.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Tolvaptan for treating autosomal dominant polycystic kidney disease.
36. 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.
37. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of tolvaptan for treating autosomal dominant polycystic kidney disease on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
- 37.1. The appropriateness of the subgroup with CKD stage 2 and 3
- 37.2. The company's revised base case including the revised assumptions used in the cost effectiveness model and how this differed to the preferred assumptions used by the ERG.
- 37.3. Discussions relating to quality of life, treatment-related utility decrements and health state utility values, including those presented from OVERTURE
- 37.4. The most plausible ICER
38. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

39. 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.
40. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

41. The Committee continued to discuss the clinical and cost effectiveness of tolvaptan for treating autosomal dominant polycystic kidney disease.
42. 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

43. Tuesday 4 August 2015, 10am to 5pm at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.