

Highly Specialised Technologies Evaluation Committee Meeting

Minutes: Confirmed

Date and Time: 28 June 2016, 9:30am to 4:00pm

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

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| Present: | 1. Dr Peter Jackson | Present for all notes |
| | 2. Prof Ron Akehurst | Present for all notes |
| | 3. Dr Ayesha Ali | Present for all notes |
| | 4. Sotiris Antoniou | Present for all notes |
| | 5. Paul Arundel | Present for all notes |
| | 6. Sarah Davis | Present for all notes |
| | 7. Stuart Davies | Present for all notes |
| | 8. Carrie Gardner | Present for all notes |
| | 9. Jeremy Manual | Present for all notes |
| | 10. Dr Shehla Mohammed | Present for all notes |
| | 11. Francis Pang | Present for all notes |
| | 12. Linn Phipps | Present for all notes |
| | 13. Dr Mark Sheehan | Present for all notes |
| | 14. Dr Glenda Sobey | Present for all notes |
| | 15. Professor Lesley Stewart | Present for all notes |

In attendance:

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| Mirella Marlow | Programme Director, National Institute for Health and Care Excellence | Present for all notes |
| Sheela Upadhyaya | Associate Director, National Institute for Health and Care Excellence | Present for all notes |
| Joanne Ekeledo | Project Manager, National Institute for Health and Care Excellence | Present for all notes |
| Orsolya Balogh | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 1 to 12 |
| Raisa Sidhu | Technical Adviser, National Institute for | Present for notes 1 to 12 |

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| | Health and Clinical Excellence | |
| Mandy Tonkinson | Administrator National Institute for Health and Clinical Excellence | Present for all notes |
| Ian Watson | Technical Adviser, National Institute for Health and Clinical Excellence | Present for notes 16 to 26 |
| Thomas Paling | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 16 to 26 |
| Maria Westwood | ERG Representative | Present for notes 4 to 12 |
| Nasuh Buyukkaramikli | ERG Representative | Present for notes 4 to 12 |
| Dr Anna Stears | Clinical Expert | Present for notes 4 to 12 |
| Prof Tricia Tan | Clinical Expert | Present for notes 4 to 12 |
| Rebecca Sanders | Patient Expert | Present for notes 4 to 12 |
| Katharine Mole | Patient Expert | Present for notes 4 to 12 |
| Fiona Marley | Commissioning Expert | Present for notes 4 to 12 and 16 to 23 |
| Non-public observers: | | |
| Helen Barnett | Editor, National Institute for Health and Clinical Excellence | Present for all notes |
| Adam Brooke | Technical Analyst, National Institute for Health and Clinical Excellence | Present for all notes |
| Heidi Livingstone | Senior Public Involvement Adviser, National Institute for Health and Clinical Excellence | Present for notes 4 to 12 |

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 evaluations of metreleptin for treating lipodystrophy and velmanase alfa for treating alpha-mannosidosis.
2. The Chair welcomed Dr Paul Arundel to their first meeting as a member of the Evaluation Committee

Any other Business

3. None.

Evaluation of metreleptin for treating lipodystrophy [ID861]

Part 1 – Open session

4. The Chair welcomed the invited experts: Nasuh Buyukkaramikli, Fiona Marley Katharine Mole, Rebecca Sanders, Dr Anna Stears, Prof Tricia Tan and Nasuh Buyukkaramikli to the meeting and they introduced themselves to the Committee.
5. The Chair welcomed company representatives from Aegerion to the meeting.
6. The Chair asked all Committee members to declare any relevant interests
 - 6.1. Professor Ron Akehurst, Dr Ayesha Ali, Sotiris Antoniou, Paul Arundel, Sarah Davis, Stuart Davies, Carrie Gardner, Jeremy Manuel, Dr Shehla Mohammed, Francis Pang, Linn Phipps, Dr Mark Sheehan, Dr Glenda Sobey, Professor Lesley 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 Evaluation of metreleptin for treating lipodystrophy
7. The 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 evaluation of metreleptin for treating lipodystrophy.
8. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their 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 evaluation of metreleptin for treating lipodystrophy.
9. The Chair introduced the lead team, Sotiris Antoniou, Linn Phipps and Carrie Gardner who gave presentations on the clinical effectiveness and cost effectiveness of metreleptin for treating lipodystrophy.

10. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
11. 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.
12. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the evaluation 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 metreleptin for treating lipodystrophy.
 - 14.1. The committee decision was based on consensus.
15. The Committee instructed the technical team to prepare the [Evaluation Consultation Document (ECD) or Final Evaluation Determination (FED)] in line with their decisions.

Evaluation of velmanase alfa for treating alpha-mannosidosis

Part 1 – Open session

16. The Chair welcomed company representatives from Chiesi Ltd to the meeting.
17. The Chair asked all Committee members to declare any relevant interests
 - 17.1. Professor Ron Akehurst, Dr Ayesha Ali, Sotiris Antoniou, Paul Arundel, Stuart Davies, Carrie Gardner, Jeremy Manuel, Dr Shehla Mohammed, Francis Pang, Linn Phipps, Dr Mark Sheehan, Dr Glenda Sobey, Professor Lesley 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 evaluation of velmanase alfa for treating alpha-mannosidosis.
 - 17.2. Sarah Davis declared a non-personal specific financial interest as part of his team had produced the assessment report for this evaluation, although he had not been directly involved.
 - 17.2.1 It was agreed that this declaration would not prevent Sarah Davis from participating in this section of the meeting.
 - 17.3. Jeremy Manuel declared a personal non-specific financial interest due to his role as co-founder and Director of the Gauchers Association which forms part of the LSD collaborative to which the MPS Society is also a member. The MPS Society support patients with alpha-mannosidosis.

17.3.1 It was agreed that this declaration would not prevent Jeremy Manuel from participating in this section of the meeting.

18. The Chair asked all other invited guests (experts, not including observers) to declare their relevant interests.
 - 18.1. 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 evaluation of velmanase alfa for treating alpha-mannosidosis
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 evaluation of velmanase alfa for treating alpha-mannosidosis.
20. The Chair introduced the key themes arising from the consultation responses to the Evaluation Consultation Document (ECD) received from consultees, commentators and through the NICE website.
21. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
22. 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.
23. The Chair then thanked the company representatives for their attendance, participation and contribution to the evaluation and they left the meeting.

Part 2 – Closed session

24. Discussion on confidential information continued. This information was supplied by the company.
25. The Committee continued to discuss the clinical and cost effectiveness of velmanase alfa for treating alpha-mannosidosis
 - 25.1. The committee decision was based on consensus.
26. The Committee instructed the technical team to prepare the [Evaluation Consultation Document (ECD) or Final Evaluation Determination (FED)] in line with their decisions.

Date, time and venue of the next meeting

27. Wednesday 25 July 2018 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.