Highly Specialised Technologies Evaluation Committee Meeting

Minutes: Confirmed

Date and Time: Thursday 29 August 2019

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

Present:

1.Dr Peter Jackson Present for all notes

2.Prof Ron Akehurst Present for notes 10-15

3.Sotiris Antoniou Present for all notes

4.Matt Smith 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.Francis Pang Present for notes 1-9

10. Linn Phipps Present for all notes

11. Dr Mark Sheehan Present for all notes

12.Dr Glenda Sobey Present for all notes

In attendance:

Helen Knight, 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

Sohaib Ashraf, Technical Analyst

National Institute for Health and Care Excellence Present for notes 1 to 9

Ian Watson, Technical Adviser

National Institute for Health and Clinical Excellence Present for notes 1 to 9

Thomas Strong, Technical Adviser

National Institute for Health and Clinical Excellence Present for notes 10-15

Rashida Akhtar, Administrator

National Institute for Health and Clinical Excellence Present for all notes

Ayesha Ali, NHS England commissioning expert Present for 1-8 notes and thereafter 10-14

Tamir Singer,NHS England commissioning expert Present for notes 10-14

Dr Karolina Stepien, Clinical Expert Present for notes 1 to 8

Dr Alex Broomfield, Clinical Expert Present for notes 1 to 8

Rebecca Brandon, Patient Expert Present for notes 1 to 8

Sophie Thomas, Patient Expert Present for notes 1 to 8

Paul Gissen, Clinical Expert Present for notes 10-14

Gail Rich, Patient Expert Present for notes 10-14

Lucy Carroll, Patient Expert Present for notes 10-14

Samantha Barber, Patient Expert Present for notes 10-14

Matthew Stevenson, ERG Representative Present for notes 1 to 8

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 Velmanase alfa for treating alpha-mannosidosis and Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2.
2. The Chair informed the Committee of the non-public observers at this meeting: Ann Greenwood, Jeanette Kusel, and Mandy Tonkinson.
3. Apologies were received from Jeremy Manuel, Dr Shehla Mohammed and Professor Lesley Stewart.

Any other Business

1. None

Evaluation of Velmanase alfa for treating alpha-mannosidosis [ID800]

Part 1 – Open session

1. The Chair welcomed the invited experts: Ayesha Ali, Dr Alex Broomfield, Rebecca Brandon, Dr Karolina Stepien, Matthew Stevenson and Sophie Thomas to the meeting and they introduced themselves to the Committee.
2. The Chair welcomed company representatives from Chiesi to the meeting.
3. The Chair asked all Committee members to declare any relevant interests
   1. All present Committee members 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.
   2. Professor Ron Akehurst declared a personal specific financial interest as his team had produced the assessment report for this evaluation, which he was directly involved.

7.2.1 It was agreed that this declaration would prevent Professor Ron Akehurst participating in this section of the meeting.

1. The Chair asked all NICE Staff to declare any relevant interests.
   1. All NICE staff 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.
2. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
   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.
3. 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
4. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
5. 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.
6. 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

1. Discussion on confidential information continued. This information was supplied by the company. Clinical and patient experts, ERG and company representatives excused.
2. The Committee continued to discuss the clinical and cost effectiveness of Velmanase alfa for treating alpha-mannosidosis.
3. The committee decision was based on consensus.
4. The Committee instructed the technical team to prepare the Final Evaluation Determination (FED) in line with their decisions.

Evaluation of Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2 [ID943]

Part 1 – Open session

1. The Chair welcomed the invited experts: Ayesha Ali, Samantha Barber, Lucy Carroll, Paul Gissen, Gail Rich, and Tamir Singer to the meeting and they introduced themselves to the Committee.
2. The Chair welcomed company representatives from BioMarin to the meeting.
3. The Chair asked all Committee members to declare any relevant interests
   1. All present Committee members 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 Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2.
4. The Chair asked all NICE Staff to declare any relevant interests.
   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 Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2.
5. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
   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 Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2.
6. 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.
7. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
8. 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.
9. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the evaluation and they remained for part 2a of the meeting.

Part 2 – Closed session

1. **Start part 2a** - Discussion on confidential information continued. This information was supplied by the company. Company representatives and NHS England experts remained for the discussion.
2. **Start part 2b** - NHSE and company representatives excused. Committee agrees recommendation(s)

1. The Committee continued to discuss the clinical and cost effectiveness of Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2.
   1. The committee decision was based on consensus.
2. The Committee instructed the technical team to prepare the Final Evaluation Determination (FED)] in line with their decisions.

**Date, time and venue of the next meeting**

1. Thursday 31 October 2019, 10am – 5pm at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.