NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Highly Specialised Technologies Evaluation Committee (HSTEC) meeting minutes

**Minutes:** Confirmed

**Date and time:** Wednesday 13 April at 09:30am

**Location:** Via Zoom

## Attendees

Committee members present

1. Dr Peter Jackson (Chair) Present for all items
2. Dr Paul Arundel (Vice Chair) Present for all items
3. Professor Ron Akehurst Present for items 5 – 5.2.2
4. Sotiris Antoniou Present for all items
5. Professor Philip Beales Present for items 1 – 4.2.2
6. Stuart Davies Present for all items
7. Sarah Davis Present for all items
8. Carrie Gardner Present for all items
9. Francis Pang Present for all items
10. Karen Samuels Present for all items
11. Dr Mark Sheehan Present for all items

NICE staff present

Richard Diaz, Associate Director Present for all items

Gavin Kenny, Project Manager Present for items 1 – 4.2.2

Daniel Davies, Project Manager Present for items 5 – 5.2.2

Thomas Strong, Health Technology Assessment Advisor Present for items 1 – 4.2.2

Sally Doss, Health Technology Assessment Advisor Present for all items 1 - 4.2.2

Zain Hussain, Health Technology Assessment Analyst Present for items 1 – 4.2.2

Rachel Ramsden, Health Technology Assessment Analyst Present for items 5 – 5.1.3

Emily Eaton-Turner, Technical Analyst, Commercial Risk Present for all items

Catrin Austin, Technical Analyst. Present for items 1 – 4.2.2

Anita Sangha, Technical Analyst. Present for items 1 - 4.2.2

Claire Hawksworth, Technical Analyst, Evidence Generation. Present for all items

Korin Knight, Senior Medical Editor Present for items 1 – 4.2.2

Emma Barnett, Senior Medical Editor Present for items 5 – 5.1.3

Heidi Livingstone, Senior Advisor, PiP Present for items 5 – 5.1.3

Mandy Tonkinson, Advisor, PiP Present for items 1 - 4.1.2

Lyn Davies, Coordinator, Corporate Office Present for items 1 – 4.1.2 and items 5 – 5.1.3

Ismahan Abdullah, Administrator, TA Present for items 1 - 4.2.2

Emma Gordon, Administrator, TA Present for items 5 – 5.2.2

Laura Kelly, Administrator, COT Present for items 1 – 4.2.2

Catherine Pank, Assistant Project Manager, COT Present for items 5 – 5.2.2

External assessment group representatives present

Maiwenn Al, Kleijnen Systematic Reviews Ltd (KSR) Present for items 1 – 4.1.3

Sue O’Meara, Kleijnen Systematic Reviews Ltd (KSR) Present for items 1 – 4.1.3

Robert Wolff, Kleijnen Systematic Reviews Ltd (KSR) Present for items 1 – 4.1.3

Amanda Brand, PenTAG Health Technology Assessment Present for items 5 – 5.1.3

Brian O’Toole, PenTAG Health Technology Assessment Present for items 5 – 5.1.3

Experts present

Jess Doyle, Head of Insight, Metabolic Support UK. Present for items 1 - 4.1.3

Becky Shaw, Patient Expert, nominated by Metabolic Support UK. Present for items 1 – 4.1.3

Dr Wesley Hayes, Consultant Paediatric Nephrologist, Great Ormond Street Hospital, NHS Foundation Trust. Present for items 1 – 4.1.3

Dr Sally-Anne Hulton, Consultant Paediatric Nephrologist, Birmingham Women's and Children's NHS Foundation Trust. Present for items 1 – 4.1.3

Dr Shabbir Moochhala, Consultant Nephrologist, Royal Free London NHS Foundation Trust. Present for items 1 - 4.1.3

Fiona Marley, Head of Highly Specialised Commissioning, NHS England. Present for all items

Dr Pooja Sachdev, Consultant in Paediatric Diabetes & Endocrinology, Royal College of Paediatrics & Child Health. Present for items 5 – 5.1.3

Professor Sadaf Farooqi, Principal Research Fellow and Professor of Metabolism and Medicine, University of Cambridge & Addenbrooke’s Hospital. Present for items 5 – 5.1.3

Debbie Potter, Patient Expert, nominated by Professor Sadaf Farooqi. Present for items 5 – 5.1.3

Alexander Potter, Patient Expert nominated by Professor Sadaf Farooqi . Present for items 5 - 5.1.3

NICE Observers present

Michelle Green, Health Technology Assessment Advisor, NICE. Present for items 1 – 4.1.

David Chandler, Appeal Panel Lay Member, NICE. Present for all items.

Paul Robinson, Appeal Panel Member, NICE. Present for items 1 – 5.1.3

## Minutes

### Introduction to the meeting

* 1. The chair welcomed members of the committee and other attendees present to the meeting.
  2. The chair noted apologies from Jeremy Manuel, Shehla Mohammed, Matt Smith, Lesley Stewart, Karen Whitehead and Philip Beales (Topic 2 only)

### News and announcements

* 1. None.

### Minutes from the last meeting

* 1. The committee approved the minutes of the committee meeting held on Wednesday 16 February 2022

### Evaluation of Lumasiran for treating primary hyperoxaluria type 1 [ID3765]

* 1. Part 1 – Open session
     1. The chair welcomed the invited professional experts, external assessment group representatives, members of the public and company representatives from Alnylam.
     2. The chair asked all committee members, professional experts, external assessment group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Professor Ron Akehurst declared a direct financial interest prior to the meeting, as his company has provided advice to Alnylam on this product. It was agreed that this declaration would prevent Professor Akehurst from attending this discussion.
* Dr Mark Sheehan declared a direct financial interest due to receiving payment by Alnylam, via Clinigen (who was advising the company) for providing feedback on ethical issues in their planned Early Access to Medicines Scheme for Lumasiran. It was agreed that this declaration would not prevent Dr Sheehan from attending this discussion
* Jess Doyle declared a non-financial personal and professional interest, due being Head of Insight at Metabolic Support UK and due to being a member of various boards and directives, including the Metabolic Clinical Referencing Group - but nothing in relation to this technology. Jess Doyle also declared an indirect financial interest as Metabolic Support UK has historically received core funding for individual support, empowerment and advocacy services from the pharmaceutical company linked to this appraisal, but not within the last 12 months. It was agreed that this declaration would not prevent Jess Doyle from providing expert advice in this discussion.
* Dr Sally-Anne Hulton declared a direct financial interest due to having received consultation fees, honoraria, and travel grant support from Alnylam and Dicerna pharmaceuticals. Dr Hulton also declared a direct non-financial interest, having have participated as Chief Investigator for a number of trials on behalf of Alnylam and Dicerna, and a further indirect interest as they have received consultation fees and a travel grant from Chiesi, a pharmaceutical company engaged in rare disease therapies. It was agreed that these declarations would not prevent Dr Hulton from providing expert advice in this discussion.
* Dr Shabbir Moochhala declared a direct financial interest as they are a Scientific advisory board member for Alnylam and Dicerna, and work in clinical private practice for renal medicine. Dr Moochhala also declared a direct non-financial interest, having worked in the following positions: Chair of NHS Rare Disease Collaborative Network for hyperoxaluria, Chair of the renal Rare Disease Group for hyperoxaluria, Steering committee member of OxalEurope, Guidelines committee member of OxalEurope, Chief Investigator for Alnylam Illuminate-C study, Principal Investigator for Alnylam BONAPH1DE Phase IV study in PH1 and Chief Investigator for 3 Dicerna trials and one trial in enteric hyperoxaluria. It was agreed that these declarations would not prevent Dr Moochhala from providing expert advice in this discussion.
* Dr Wesley Hayes declared an indirect interest as they have acted as co-investigator on Illuminate clinical trials and had received travel expenses when attending the international trial investigator meeting. It was agreed that this declaration would not prevent Dr Hayes would from providing expert advice during this discussion.
  + 1. The Chair led a discussion of the evidence presented to the committee. This information was presented to the committee by Carrie Gardner (Clinical), Francis Pang (Cost) and Dr Mark Sheehan (Lay).
  1. Part 2 – closed session (members of the public, company representatives, external assessment group representatives and clinical and experts were asked to leave)
     1. The committee then agreed on the content of the Evaluation Consultation Document (ECD) or Final Evaluation Determination (FED). The committee decision was reached by consensus.

4.2.2 The committee asked the NICE technical team to prepare the Evaluation Consultation Document (ECD) in line with their decisions.

### Evaluation of Setmelanotide for treating obesity caused by LEPR or POMC deficiency [ID3764]

* 1. Part 1 – Open session
     1. The chair welcomed the invited professional experts, external assessment group representatives, members of the public and company representatives from Rhythm Pharmaceuticals Inc.
     2. The chair asked all committee members, professional experts, external assessment group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* No conflicts of interest were declared for the technology.
  + 1. The Chair led a discussion of the consultation comments presented to the committee. This information was presented to the committee by the Chair, Dr Peter Jackson.
  1. Part 2 – Closed session (company representatives, professional experts, external assessment group representatives and members of the public were asked to leave the meeting).
     1. The committee then agreed on the content of the Evaluation Consultation Document (ECD) or Final Evaluation Determination (FED). The committee decision was reached by consensus.
     2. The committee asked the NICE technical team to prepare the Final Evaluation Determination (FED) in line with their decisions.

### Date of the next meeting

The next meeting of the Highly Specialised Technologies Evaluation Committee (HSTEC) will be held on Wednesday 8 June 2022 and will start promptly at 09:30am.