NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Technology Appraisal Committee C meeting minutes

**Minutes:** Confirmed

**Date:** Tuesday 11 May 2021

**Location:** Via Zoom

## **Committee members present**

1. Professor Steve O’Brien (Chair) Present for all items
2. Dr Peter Selby (Vice Chair) Present for all items
3. Dr Alex Cale Present for all items
4. Michael Chambers Present for all items
5. Dr Prithwiraj Das Present for all items
6. Dr David Foreman Present for all items
7. Dr Robert Forsyth Present for all items
8. Dr Natalie Hallas Present for all items
9. John Hampson Present for all items
10. Dr Nigel Langford Present for all items
11. Dr Andrea Manca Present for all items
12. Iain McGowan Present for all items
13. Kirandip Moyo Present for items 1 to 2.2.2
14. Dr Richard Nicholas Present for all items
15. Ugochinyere Nwulu Present for items
16. Stella O’Brien Present for all items
17. Professor Subhash Pokhrel Present for all items
18. Professor Andrew Renehan Present for all items
19. Professor Matthew Stevenson Present for all items
20. Professor Paul Tappenden Present for items 1 to 2.2.2

## **NICE staff present:**

Helen Knight, Programme Director Present for items 1 to 2.2.2

Linda Landells, Associate Director Present for items 1 to 2.2.2

Ross Dent, Associate Director Present for items 3 to 3.2.2

Louise Jafferally, Project Manager Present for items 1 to 2.1.3 & 3 to 3.2.2

Kate Moore, Project Manager Present for items 1 to 2.2.2

Alexandra Filby, Health Technology Assessment Adviser Present for items 3 to 3.2.2

Alan Moore, Health Technology Assessment Analyst Present for items 1 to 2.2.2

Abi Senthinathan, Health Technology Assessment Analyst Present for items 3 to 3.2.2

Sarah Wilkes, Health Technology Assessment Analyst Present for all items

Gareth Murphy, Business Analyst, RIA Present for all items

Benjamin Pearce, Senior Medical Editor Present for items 1 to 2.2.2

Ria Skelton, Senior Medical Editor Present for items 3 to 3.1.3

Emily Eaton-Turner, Technical Adviser, Commercial Risk Assessment, Present for items 3 to 3.1.3

Ella Livingstone, Technical Adviser, Commercial Risk Assessment, Present for all items

Stevie Okoro, Technical Analyst, Commercial Risk Assessment, Present for items 3 to 3.2.2

Thomas Strong, Technical Adviser, Managed Access Present for items 3 to 3.2.2

Alexa Forrester, Health Technology Adoption Manager Present for items 1 to 2.2.2

Mandy Tonkinson, Public Involvement Adviser, PIP, Present for items 1 to 2.1.3 & 3 to 3.1.3

Catherine Pank, Assistant Project Manager, COT Present for items 2 to 3.2.2

Rosalee Mason, Coordinator, MIP Present for items 1 to 2.1.3 & 3 to 3.1.3

Gemma Smith, Coordinator, COT Present for all items

Celia Mayers, Administrator Present for items 1 to 2.2.2

Pratit Shah, Administrator Present for items 3 to 3.2.2

Victoria Hall, MIP Support Present for items 1 to 2.1.3 & 3 to 3.1.3

## **External group representatives present:**

Mary Jordan, Warwick Evidence Present for items 1 to 2.1.3

Daniel Todkill, Warwick Evidence Present for items 1 to 2.1.3

Emma Hock, School of Health and Related Research (ScHARR), Present for items 3 to 3.1.3

Paul Tappenden, School of Health and Related Research (ScHARR), Present for items 3 to 3.1.3

## **Clinical & patient experts present:**

Suzy Heafield, Commissioning expert, NHS England, Present for items 1 to 2.1.3

Dr Alan Jones, Consultant Physician, clinical expert nominated by SANOFI – AVENTIS Present for items 1 to 2.1.3

Professor Kausik Ray, Professor of Public Health and Honorary Consultant Cardiologist, clinical expert nominated by Novartis Pharmaceuticals UK Ltd, Present for items 1 to 2.1.3

Simon Williams, Patient expert nominated by HEART UK- The Cholesterol Charity
Present for items 1 to 2.1.3

Dr Ayesha Ali, NHS Commissioning expert, NHS England, Present for items 3 to 3.1.3

Dr Anne-Marie Childs, Consultant Paediatric Neurologist, clinical expert nominated by Muscular Dystrophy UK & Roche Products Ltd, Present for items 3 to 3.1.3

Lucy Frost, patient expert nominated by TreatSMA, Present for items 3 to 3.1.3

Dr Channa Hewamadduma, Consultant neurologist, clinical expert nominated by Muscular Dystrophy UK, Present for items 3 to 3.1.3

Satvinder Mahal, Principal Pharmacist, Neurosciences, clinical expert nominated by Neonatal and Paediatric Pharmacists Group, Present for items 3 to 3.1.3

Liz Ryburn, Patient expert nominated by SMA UK and Muscular Dystrophy UK, Present for items 3 to 3.1.3

Andi Thornton, Patient expert nominated by TreatSMA, Present for items 3 to 3.1.3

### Introduction to the meeting

* 1. The chair Professor Steve O’Brien welcomed members of the committee and other attendees present to the meeting.

### Appraisal of inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia [ID1647]

* 1. Part 1 – Open session
		1. The chair welcomed the invited clinical and patient experts, external group representatives, members of the public and company representatives from Novartis.
		2. The chair asked all committee members, clinical and patient experts, external group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Dr Prithwiraj Das declared non-financial professional interests as he works at AstraZeneca UK as the Head of Market Access for Respiratory and Immunology therapies and Vaccines. He also noted that rosuvastatin is listed as one of the comparators but to his knowledge this is not currently promoted, and he has not been involved in work related to this appraisal.
* It was agreed that his declaration would not prevent Dr Das from participating in this section of the meeting.
* Dr Richard Nicholas declared a financial interest as he has attended paid advisory boards with Roche and Novartis for treatment in an unrelated area (MS).
* It was agreed that his declaration would not prevent Dr Nicholas from participating in this section of the meeting.
* Dr Alan Jones declared financial interests as he has been the local Principal Investigator at UHB for the Oxford University sponsored ORION 4 study using inclisiran or placebo in the secondary prevention of CVD.
* It was agreed that his declaration would not prevent Dr Jones from providing expert advice to the committee.
* Professor Kausik Ray declared financial interests as he has received honoraria for his role in ORION trial programme and acting as a consultant to Novartis and prior to that the Medicines Company. He has received honoraria from Sanofi, Amgen, Daiichi Sankyo, Esperion, Lilly, Regeneron, New Amsterdam, Silence Therapeutics, Pfizer, and Astra Zeneca for acting as a consult/ advisor on atherosclerosis and lipid lowering therapies and has also received grants from Imperial-Amgen, Sanofi, Regeneron, Daiichi-Sankyo, MSD, Pfizer
* It was agreed that his declaration would not prevent Professor Ray from providing expert advice to the committee.
* Simon Williams declared indirect financial interests as HEART UK - The Cholesterol Charity has recently started work with Novartis in a different therapy area (LPa) and a CVD collaborative they are about to begin work on an education programme and Novartis are also sponsoring their conference.
* It was agreed that his declaration would not prevent Mr Williams from providing expert advice to the committee.
* No further conflicts of interest were declared for this item.
	+ 1. The Chair introduced the lead team Dr Andrea Manca, Kirandip Moyo and Stella O’Brien who gave presentations on the clinical effectiveness and cost effectiveness of inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia.
	1. Part 2 – Closed session [company representatives, clinical and patient experts, external group representatives and members of the public were asked to leave the meeting]
		1. The committee then agreed on the content of the Appraisal Consultation Document [ACD] or Final Appraisal Determination [FAD]. The committee decision was reached by consensus..
		2. The committee asked the NICE technical team to prepare the Appraisal Consultation Document [ACD] or Final Appraisal Determination [FAD] in line with their decisions.

### Appraisal of risdiplam for treating spinal muscular atrophy in children and adults [ID1631]

* 1. Part 1 – Open session
		1. The chair Professor Steve O’Brien welcomed the invited clinical, patient and NHS commissioning experts, external group representatives, members of the public and company representatives from Roche.
		2. The chair asked all committee members, clinical and patient experts, external group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Michael Chambers declared financial interests as he has recently been involved in co-ordinating a training programme in real world evidence for Roche Pharmaceuticals (manufacturer of risdiplam), but this has not involved any specific consideration of Roche products.
* It was agreed that his declaration would not prevent Mr Chambers from participating in this section of the meeting.
* Dr Prithwiraj Das declared non-financial professional interests as he works at AstraZeneca UK as the Head of Market Access for Respiratory and Immunology therapies, and Vaccines
* It was agreed that his declaration would not prevent Dr Das from participating in this section of the meeting.
* Dr Robert Forsyth declared non-financial professional interests as he is a paediatric neurologist and whilst not directly involved in the care of neuromuscular diseases (such as SMA) in children, he has made the diagnosis of SMA in children. He also knows many if not most of the paediatric neurologists caring for SMA in the UK professionally. He was also asked to act as a non-voting member/advisor for the nusinersin MAOC.
* It was agreed that his declarations would not prevent Dr Forsyth from participating in this section of the meeting.
* Dr Richard Nicholas declared a financial interest as he has attended paid advisory boards with Roche and Novartis for treatment in an unrelated area (MS).
* It was agreed that his declaration would not prevent Dr Nicholas from participating in this section of the meeting.
* Professor Matthew Stevenson declared a non-financial professional interest as ScHARR-TAG carried out the work for risdiplam and he had peer reviewed the work.
* It was agreed that his declaration would not prevent Professor Stevenson from participating in discussions in this section of the meeting however he is prevented from being a voting committee member if a vote is required to determine the outcome of this appraisal.
* Dr Anne-Marie Childs declared financial and professional interests as she has received professional fees to contribute to advisory boards for Roche, Biogen and Avexis in relation to drug development in SMA, she is a PI for iSMAC and REACH in Leeds Children’s Hospital and is also a medical trustee for SMA UK and a member of the NHSE clinical panel supporting the MAA for nusinersen.
* It was agreed that her declaration would not prevent Dr Childs from providing expert advice to the committee.

Dr Channa Hewamadduma declared financial and professional interests as he has received payment from Biogen for delivering a talk on nusinersen treatment in adult patients. He has also received payment for being on an advisory board of clinical experts for critical analysis of Roche clinical trial dataset, has taken part in two 'one off' advisory roles to Roche in critical appraisal of evidence for risdiplam and Roche had organised for him to attend the SMA Europe meeting in Feb 2020.

* Roche provided him with a travel grant which enabled him to attend the SMA conference and he has given a talk on nusinersen in adult SMA patients at a webinar held by Biogen. In addition to this he is developing PROMS for adult SMA patients in collaboration with Biogen.
* It was agreed that his declaration would not prevent Dr Hewamadduma from providing expert advice to the committee.
* No further conflicts of interest were declared for this item.

* + 1. The Chair introduced the lead team Dr Natalie Hallas, Stella O’Brien and Professor Subhash Pokhrel, who gave presentations on the clinical effectiveness and cost effectiveness of risdiplam for treating spinal muscular atrophy in children and adults.
	1. Part 2 - Closed session [company representatives, clinical and patient experts, external group representatives and members of the public were asked to leave the meeting].
		1. The committee then agreed on the content of the Appraisal Consultation Document [ACD] or Final Appraisal Determination [FAD]. The committee decision was reached by consensus..
		2. The committee asked the NICE technical team to prepare the Appraisal Consultation Document [ACD] or Final Appraisal Determination [FAD] in line with their decisions.

### Date of the next meeting

The next meeting of the Technology Appraisal Committee C will be held on Wednesday 16 June 2021 and will start promptly at 9.30am.