NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Technology Appraisal (Committee A) meeting minutes

**Minutes:** Confirmed

**Date and time:** Tuesday 2 February 2021, 9:30am – 17:20pm

**Location:** Zoom video conference

## **Attendees**

Committee members present:

1. Dr Jane Adam (Chair) Present for all items
2. Dr Brian Shine (Vice Chair) Present for all items
3. Mr Peter Baker Present for items 1 to 5
4. Mr Richard Ballerand Present for all items
5. Dr Andrew Champion Present for all items
6. Dr Justin Daniels Present for all items
7. Dr Steve Edwards Present for items 1 to 3
8. Dr Rita Faria Present for items 1 to 5.1
9. Professor Khalida Ismail Present for all items
10. Dr Bernard Khoo (TAC D) Present for items 6 and 7
11. Professor G.J. Melendez-Torres Present for items
12. Professor Stephen O’Brien (TAC C) Present for items 4 to 7
13. Mrs Becky Pennington Present for all items
14. Ms Pamela Rees Present for all items
15. Dr Stephen Sharp Present for all items
16. Mr Min Ven Teo Present for all items
17. Dr Alice Turner Present for items 3 to 5
18. Dr Roger Whittaker Present for all items

NICE staff present:

Helen Knight, Programme Director Present for item 3

Janet Robertson, Associate Director Present for all items

Natalie Spray, Programme Manager Present for items 1 to 3.1

Thomas Feist, Project Manager Present for items 1 to 5.1, 6 and 7

Jeremy Powell, Project Manager Present for items 4 and 5

Joanna Richardson, Technical Advisor Present for items 1 to 3

George Braileanu, Technical Advisor Present for items 1 to 3

Lorna Dunning, Technical Advisor Present for items 4 and 5

Emma Douch, Technical Advisor Present for items 4 and 5

Zoe Charles, Technical Analyst Present for items 6 and 7

Emily Leckenby, Technical Lead Present for items 6 and 7

Heidi Livingstone, Senior Public Involvement Adviser Present for items 4 and 5.1

Laura Marsden, Public Involvement Advisor Present for items 1 to 3.1, 4 to 5.1 and 6.1

Sally Taylor, Public Involvement Coordinator Present for items 1 to 3.1

Lucinda Evans, Coordinator Present for items 1 to 3.1and 6.1

Victoria Hall, Coordinator Present for items 4 and 5.1

Rosalee Mason, Coordinator Present for items 4 and 5.1

Mira Patel, Coordinator Present for all items

Sandra Robinson, Coordinator Present for items 1 to 3.1 and 6.1

Gemma Smith, Coordinator Present for item 3

Marcia Miller, Administrator Present for items 1 to 3 and 6 to 7

Daniel Greenwood, Assistant Administrator Present for items 1 to 5.1 and 6 to 7

External group representatives present:

Jeanette Greenhalgh, Clinical Lead, Liverpool Reviews and Implementation Group, Present for items 1 to 3.1

James Mahon, Health Economist, Liverpool Reviews and Implementation Group, Present for items 1 to 3.1

Gemma Marceniuk, Health Economist, BMJ TAG Present for items 4 to 5.1

Vicky Wakefield, Principal HTA Analyst, BMJ TAG Present for items 4 to 5.1 and 6.1

Tracey Jhita, Health Economics Manager, BMJ TAG Present for item 6.1

Professional experts present:

Dr Robin Lachmann, Consultant in Metabolic Medicine, UCLH Present for items 1 to 3.1

Dr Hugh Lemonde, Consultant Paediatric Inherited Metabolic Disease, Evelina Hospital Present for items 1 to 3.1

Claire Foreman, Head of Acute Programmes, Specialised Commissioning, NHSE&I, Present for items 1 to 3.1

Professor Anita MacDonald, Consultant Dietitian, Birmingham Children’s Hospital , Present for items 1 to 3.1

Ms Sharon Buckley, patient advocate Patient expert nominated by The National Society for Phenylketonuria, Present for items 1 to 3.1

Dr Deepa Jayakody Arachchillage, Consultant Haematologist, Imperial College Healthcare NHS Trust

Present for items 4 and 5.1

Mr Diederik Bulters, Consultant Neurosurgeon, UH Southampton Present for items 4 and 5.1

Mr Patrick Grover, Consultant Neurosurgeon, UCLH Present for items 4 and 5.1

Professor Elizabeth Warburton, Stroke Physician, Addenbrooke’s Hospital, Present for items 4 and 5.1

Dr Andrew Veitch, Consultant Gastroenterologist, British Society of Gastroenterology, Present for items 4 and 5.1

Ms Diane Eaton, Consultant Project Manager, Anticoagulation UK Present for items 4 and 5.1

Professor Peter Clark, CDF clinical lead, NSHE&I Present for item 6

Dr Peter Goon, Consultant Dermatologist, NW Anglia NHS FT Present for item 6.1

Dr Paul Nathan, Consultant Medical Oncologist, Mount Vernon Cancer Centre, Present for item 6.1

Ms Nicola Jervis, Patient Support & Information Nurse Specialist, Neuroendocrine Cancer UK, Present for item 6.1

Observers present:

Sarah Bromley, Senior Medical Editor, NICE Present for items 1 to 3

Henry Cass, Associate Digital Performance Analyst, NICE Present for item 6.1

Shonagh D’Sylva, Project Manager, NICE Present for items 1 to 3

Claire Hawksworth, Technical Analyst, NICE Present for items 4 and 5

Steve Norton, HTA Analyst, NICE Present for items 1 to 3.1

Stevie Okoro, Technical Analyst, NICE Present for items 1 to 3

Benjamin Pearce, Senior Medical Editor, NICE Present for items 6 and 7

Ria Skelton, Senior Medical Editor, NICE Present for items 4 and 5

Emily Steers, Policy Manager, DHSC Present for items 6 and 7

Adam Storrow, Business Analyst – RIA, NICE Present for all items

## **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 Dr Mohit Sharma, Ms Sarah Parry and Ms Sumithra Maheswaran.

### News and announcements

* 1. None.

### Appraisal of Sapropterin for treating phenylketonuria [ID1475]

* 1. Part 1 – Open session
		1. The chair welcomed the invited professional experts, external group representatives, members of the public and company representatives from BioMarin Pharmaceuticals.
		2. The chair asked all committee members, professional experts, external group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Professor Anita MacDonald, clinical expert, declared indirect interests as Birmingham Children's Hospital PKU research fund received consultancy fees from Meta Healthcare, Arlo, Nutricia, Apr, Galen and Biomarin. Birmingham Children’s Hospital also received research funds from Nutricia, Vitaflo, Biomarin, APR, Metax, Galen, Mevalia. It was agreed that this declaration would not prevent Professor MacDonald from providing expert advice to the committee.
* Dr Hugh Lemonde, clinical expert, declared a direct financial interest as he received educational support from Biomarin, enabling attendance to the 1st and 2nd PKU Masterclasses (2017/2018). It was agreed that this declaration would not prevent Dr Lemonde from providing expert advice to the committee.
* Dr Robin Lachmann, clinical expert, declared a direct financial interest as he has an ongoing consultancy agreement with Biomarin to provide input to their PKU gene therapy programme. Prior to the committee meeting, Dr Lachmann declared a direct financial interest as he is receiving consulting fees from Nestle Health Science regarding their PKU programme (ongoing). It was agreed that these declarations would not prevent Dr Lachmann from providing expert advice to the committee.
* Prior to the meeting a patient expert declared an indirect interest and it was agreed that this declaration would not prevent them from providing expert advice to the committee.
	+ 1. No further conflicts of interest were declared for this item.
	1. Part 2 – Closed session (company representatives, professional experts, external group representatives and members of the public were asked to leave the meeting)
		1. The committee discussed confidential information submitted for this item.
		2. The committee then agreed on the content of the Appraisal Consultation Document (ACD). The committee decision was reached by consensus.
		3. The committee asked the NICE technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

### Minutes from the last meeting

* 1. The committee approved the minutes of the committee meetings held on 8 December 2020 and 5 January 2021.

### Appraisal of Andexanet alfa for reversing anticoagulation [ID1101]

* 1. Part 1 – Open session
		1. The chair welcomed the invited professional experts, external group representatives, members of the public and company representatives from Alexion Pharmaceuticals, now incorporating Portola Pharmaceuticals.
		2. The chair asked all committee members, professional experts, external group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Prior to the meeting, Dr Steve Edwards, Committee Member, declared a non-financial professional & personal interest as BMJ-TAG is the ERG for this topic. It was agreed that this declaration would prevent Dr Edwards from participating in this section of the meeting and he was asked to leave the meeting for the duration of the item.
* Prior to the meeting, Dr Deepa Jayakody Arachchillage, clinical expert, declared an indirect interest as she gave an expert lecture in a meeting supported by Portola Pharmaceuticals. There was no direct contact with Portola Pharmaceuticals as the invitation to the lecture came from PCM scientific. It was agreed that this declaration would not prevent Dr Arachchillage from providing expert advice to the committee.
* Prior to the meeting, Professor Elizabeth Warburton, clinical expert, declared several non-financial professional and personal interests as she was a local PI on various RCTs:

• Ongoing Tenecteplase (thrombolysis) trials: ATTEST – Trial Steering group committee and local PI. Have stepped down from both roles for committee.

• TASTE and TWIST trials – stepped down from local PI role. UK Thrombectomy trial.

• STABILISE – local PI (trial now finished and published) CHARM (cerebral oedema) - stepped down as local PI.

• Head positioning after stroke trial HEADPOST – local PI (trial now finished and published).

• Blood pressure after stroke trials INTERACT – Local PI (trial finished and published).

• ENCHANTED - local PI (no longer recruiting)

Professor Warburton declared further non-financial professional and personal interests as she:

• Participated in the OPTIMAS trial; a British Heart Foundation and Stroke Association funded multicentre trial on the timing of the start of anticoagulants in patients with AF following ischemic stroke.

• Was awarded the Pfizer Pharmaceuticals Grant for innovation in stroke prevention in AF after national competition via the NHS Academic Health Sciences Networks (£250,000 awarded Dec 2016)

• Is a topic advisor for the NICE CG Stroke Rehabilitation guidelines committee

• Is a Board member of the NIHR HTA Clinical Trials Advisory Panel (since 2020)

• Is the Honorary Treasurer British Association of Stroke Physicians (2020-)

• Is on the editorial board of the AHA journal Stroke (from 2020).

* It was agreed that these declarations would not prevent Professor Warburton from providing expert advice to the committee.
* Mr Diederik Bulters, clinical expert, declared a direct financial interest as he received a consultancy fee in 2016 for providing expert opinion and feedback to Portola Pharmaceuticals on Andexanet alfa. It was agreed that this declaration would not prevent Mr Bulters from providing expert advice to the committee.
* Mr Patrick Grover, clinical expert, declared a direct financial interest as he participated in two Delphi consensuses for Portola Pharmaceuticals regarding this drug, for which he was received renumeration. It was agreed that this declaration would not prevent Mr Grover from providing expert advice to the committee.

 5.1.3. No further conflicts of interest were declared for this item.

* 1. Part 2 - Closed session (company representatives, professional experts, external group representatives and members of the public were asked to leave the meeting).
		1. The committee discussed confidential information submitted for this item.
		2. The committee then agreed on the content of the Final Appraisal Determination (FAD). The committee decision was reached by consensus.
		3. The committee asked the NICE technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

### Appraisal of Avelumab for treating metastatic Merkel cell carcinoma [ID1617]

* 1. Part 1 – Open session
		1. The chair welcomed the invited professional experts, external group representatives, members of the public and company representatives from Merck Serono.
		2. The chair asked all committee members, professional experts, external group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Prior to the meeting, Dr Steve Edwards, Committee Member, declared a non-financial professional & personal interest as BMJ-TAG is the ERG for this topic. It was agreed that this declaration would prevent Dr Edwards from participating in this section of the meeting and he was asked to leave the meeting for the duration of the item.
* Prior to the meeting, Dr Paul Nathan, clinical expert, declared direct financial interests as he received compensation for advisory board, speaker’s bureau membership and institutional research funding for several companies, unrelated to this application. At the meeting, Dr Nathan declared a direct financial interest as he sat on advisory boards for Merck and Pfizer. These advisory boards were not relevant to this application. It was agreed these declarations would not prevent Dr Nathan from providing expert advice to the committee.
* Nicola Jervis, patient expert, declared an indirect interest as her employer, Neuroendocrine Cancer UK, received an unrestricted grant to produce leaflets. It was agreed this declaration would not prevent Ms Jervis from providing expert advice to the committee.
	+ 1. No further conflicts of interest were declared for this item.
	1. Part 2 - Closed session (company representatives, professional experts, external group representatives and members of the public were asked to leave the meeting).
		1. The committee discussed confidential information submitted for this item.
		2. The committee then agreed on the content of the Final Appraisal Determination (FAD). The committee decision was reached by consensus.
		3. The committee asked the NICE technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

### Date of the next meeting

The next meeting of the Technology Appraisal (Committee A) will be held on Tuesday 2 March 2021 and will start at 9:30am.