NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Technology Appraisal Committee A meeting minutes

**Minutes:** Confirmed

**Date and time:** Tuesday 7 June 2022 at 9:30am

**Location:** Virtual via Zoom

## Attendees

Committee members present

1. Dr Jane Adam (Chair) Present for all items
2. Dr Brian Shine (Vice-chair) Present for all items
3. Professor Abdallah Al-Mohammad Present for all items
4. Dr Peter Baker-Gulliver Items 4.1.3 to 6.2.2
5. Richard Ballerand Present for all items
6. Dr Andrew Champion Present for all items
7. Dr Justin Daniels Present for all items
8. Ana Duarte Present for all items
9. Dr Steve Edwards Present for all items
10. Professor Khalida Ismail Present for all items
11. Dr Fiona MacPherson Smith Present for all items
12. Hugo Pedder Present for all items
13. Dominic Pivonka Items 1 to 5.2.2
14. Dr Mohit Sharma Present for all items
15. Alan Thomas Present for all items
16. Min Ven Teo Items 1 to 5.2

NICE staff present

Helen Knight, Programme Director Items 5 to 5.2.2

Janet Robertson, Associate Director Present for all items

Thomas Feist, Project Manager Items 1 to 4.2.2 & 6 to 6.2.2

Rebecca Richardson, Assistant Project Manager Items 5 to 5.2.2

Lewis Ralph, Heath Technology Assessment Analyst Items 1 to 4.2.2

Eleanor Donegan, Heath Technology Assessment Adviser Items 5 to 5.2.2

Joanna Richardson, Health Technology Assessment Adviser Items 5 to 5.2.2

Claire Hawksworth, Heath Technology Assessment Analyst Items 5 to 5.2.2

Raphael Egbu, Heath Technology Assessment Analyst Items 5 to 5.2.2

Owen Harrison, Health Technology Assessment Analyst Items 5 to 5.2.2

Mary Hughes, Heath Technology Assessment Adviser Items 6 to 6.2.2

Alexandra Sampson, Heath Technology Assessment Analyst Items 6 to 6.2.2

Adam Storrow, Business Analyst, RIA Present for all items

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

Catrin Austin, Technical Analyst, Methods and Economics Items 6 to 6.2.2

Sarah Bromley, Senior Medical Editor Items 1 to 4.2.2

Jennifer Hacking, Senior Medical Editor Items 5 to 5.2.2

Helen Barnett, Senior Medical Editor Items 6 to 6.2.2

Ella Fitzpatrick, Public Involvement Adviser, PIP Items 1 to 4.1.3, 5 to 5.1.3 & 6 to 6.1.3

Catherine Pank, Assistant Project Manager, COT Present for all items

Lyn Davis, Coordinator, MIP Items 1 to 4.1.3, 5 to 5.1.3 & 6 to 6.1.3

Marcia Miller, Administrator, TA Items 1 to 5.2.2 & 6 to 6.2.2

Rumana Zaman, Administrator, TA Items 5 to 5 to 5.2.2

Leah Kelly, Administrator, TA Items 1 to 4.2.2

External assessment group representatives present

Jonathan Shepherd, Southampton Health Technology Assessment Centre (SHTAC), Items 1 to 4.1.3

Ines Ribeiro, Southampton Health Technology Assessment Centre (SHTAC), Items 1 to 4.1.3

Lena Al-Khudairy, Warwick Evidence Items 5 to 5.1.3

Emanuela Castelnuovo, Warwick Evidence Items 5 to 5.1.3

Willem Witlox, Kleijnen Systematic Reviews Ltd (KSR) Items 6 to 6.1.3

Robert Wolff, Kleijnen Systematic Reviews Ltd (KSR) Items 6 to 6.1.3

Clinical, Patient & NHS England experts present

Ayesha Ali, NHS Commissioning representative, NHS England, Items 1 to 4.1.3

Dr James Davison, Consultant Paediatric Metabolic Medicine, Clinical expert nominated by Sanofi, Items 1 to 4.1.3

Dr Robin Lachmann, Consultant in Inherited Metabolic Disease, Clinical expert nominated by Royal College of Physicians, Items 1 to 4.1.3

Professor Mark Eldon Roberts, Consultant Neurologist, Clinical expert nominated by Sanofi, Items 1 to 4.1.3

Gemma Seyfang, Patient expert nominated by Association for Glycogen Disease, Items 1 to 4.1.3

Baroness Celia Thomas, Patient expert nominated by Association for Glycogen Disease & Muscular Dystrophy UK, Items 1 to 4.1.3

Holly Heath, Patient expert nominated by Breast Cancer Now, Items 5 to 5.1.3

Nicola Tracey, Patient expert nominated by Breast Cancer Now, Items 5 to 5.1.2 & part of 5.1.3

Dr Alicia Okines, Clinical expert nominated by Royal College of Physicians, Items 5 to 5.1.3

Professor Peter Schmid, Clinical expert nominated by Gilead Sciences Ltd , Present for, Items 5 to 5.1.3

Ronald Presswood, Patient expert nominated by, Waldenstrom’s Macroglobulinaemia UK, Items 6 to 6.1.3

Jane Nicholson, Patient expert nominated by Waldenstrom’s Macroglobulinaemia UK, Items 6 to 6.1.3

Dr Shirley D’Sa, Clinical expert nominated by Waldenstrom’s Macroglobulinaemia UK, Items 6 to 6.1.3

Dr Dima El Sharkawi, Clinical expert nominated by the Royal College of Pathologists, Items 6 to 6.1.3

Peter Clark, Professor Peter Clark, Cancer Drug Fund Clinical Lead, NHS England, Items 5 to 6.2.2

NICE Observer present

Jon Cohen, Non-executive director and recently appointed appeal panel member, Items 1 to 5.2.2

## Minutes

### Introduction to the meeting

* 1. The chair, Dr Jane Adam, welcomed members of the committee and other attendees present to the meeting.
  2. The chair noted committee members’ apologies.

### News and announcements

* 1. None

### Minutes from the last meeting

* 1. The committee approved the minutes of the committee meeting held on Tuesday 10 May 2022

### Appraisal of avalglucosidase alfa for treating Pompe disease [ID3737]

* 1. Part 1 – Open session
     1. The chair welcomed the invited experts, external assessment group representatives, members of the public and company representatives from Sanofi S.A.
     2. The chair asked all committee members and experts, external assessment group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Nominated clinical expert Dr James Davison declared direct financial and non-financial interests as he is principal investigator on open clinical trials of avalglucosidase alfa (“Mini-COMET” study) and chief investigator on a forthcoming clinical trial of the same product (Baby COMET study) and associated observational studies, for which Sanofi is the study sponsor. He attended an advisory board in another area for Sanofi. He has attended various advisory bodies and symposia and is a member of the policy working group with NHS England reviewing doses of the current treatment. It was agreed that his declarations would not prevent Dr Davison from providing expert advice to the committee.
* Nominated clinical expert Dr Robin Lachmann declared direct financial interests as he has received honoraria for speaking and travel expenses from Sanofi Genzyme. He has also received consulting fees from Sanofi Genzyme related to olipudase alfa for acid sphingomyelinase deficiency and has received consulting fees from Biomarin and Takeda related to their gene therapy programme for phenylketonuria. Dr Lachmann has received honoraria for speaking from Amicus. It was agreed that his declarations would not prevent Dr Lachmann from providing expert advice to the committee.
* Nominated clinical expert Professor Mark Eldon Roberts declared direct financial interests as he has received honoraria for presentations and advisory boards for Sanofi and has worked with other companies in this field (Amicus, Audentes, Spark Therapeutics). He was a principal investigator in the clinical trials including the COMET study. It was agreed that his declarations would not prevent Professor Eldon Roberts from providing expert advice to the committee.
* Nominated patient expert Baroness Celia Thomas declared indirect financial interests as her nominating organisations received the following funding:
* Association for Glycogen Storage Disease UK (AGD) has received funding from Sanofi Genzyme for on-line conference series, patient education, benefits support, and community services.
* Muscular Dystrophy UK (MDUK) has received funding from Sanofi as a sponsorship for a translational research conference

Baroness Thomas is also a Trustee of MDUK. It was agreed that her declarations would not prevent Baroness Thomas from providing expert advice to the committee

* + 1. The Chair led a discussion of the evidence presented to the committee. This information was presented to the committee by the Lead Team: Dr Justin Daniels, Min Ven Teo and Richard Ballerand.
  1. Part 2 – Closed session (company representatives, clinical and patient 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 Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD). The committee decision was reached through a vote by members.
     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.
* Further updates will be available on the topic webpage in due course:

<https://www.nice.org.uk/guidance/indevelopment/gid-ta10876>

### Appraisal of sacituzumab govitecan for treating unresectable locally advanced or metastatic triple-negative breast cancer after 2 or more therapies [ID3942]

* 1. Part 1 – Open session
     1. The chair, Dr Jane Adam welcomed the invited experts, external assessment group representatives, members of the public and company representatives from Gilead Sciences Inc
     2. The chair asked all committee members and experts, external assessment group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Nominated Patient expert Holly Heath, declared indirect financial interests In Breast Cancer Now’s 2020-21 financial year they received some funding from the manufacturer Gilead towards their online living with secondary breast cancer support service. In 2021-22 financial year, Breast Cancer Now received funding from possible comparator company Roche towards their living with secondary breast cancer support service.

Breast Cancer Now does not accept any funding towards their Policy, Evidence and Influencing work which involves all their work on access to drugs.

Breast Cancer Now also launched a campaign in summer 2021 aimed at Gilead, calling on them to work with NHS England to agree an interim access agreement for Trodelvy following licensing through Project Orbis.

It was agreed that her declarations would not prevent Ms Heath from providing expert advice to the committee.

* Nominated Clinical expert Dr Alicia Okines declared direct financial interests as she has received Research funding from Pfizer and Roche, Conference support from AstraZeneca, Lilly, Leo Pharmaceuticals, Daiichi-Sankyo, Advisory Board fees from Roche, Seagen, Astra Zeneca and Daiichi-Sankyo and Speaker fees from Pfizer, Seagen, Lilly, Daiichi-Sankyo, and Gilead. She is also a principal investigator in the TROPICS-02 trial of Sacituzumab govitecan. It was agreed that her declarations would not prevent Dr Okines from providing expert advice to the committee.
* Nominated Clinical expert Professor Peter Schmid declared financial and personal interests as he has received honorarium for advisory and research boards from AstraZeneca, Bayer, Boehringer Ingelheim, Celgene, Eisai, Gilead, Merck, MSD, Novartis, Pfizer, Puma, and Roche. His institution has received grants and funding from Astellas, AstraZeneca, Genentech, Novartis, Oncogenex, Roche, Medivation and his spouse is an employee of Roche. It was agreed that his declarations would not prevent Professor Schmid from providing expert advice to the committee.
  + 1. The Chair led a discussion of the consultation comments presented to the committee. This information was presented to the committee by the Vice-chair, Dr Brian Shine and the Chair, Dr Jane Adam
  1. Part 2 – Closed session (company representatives, clinical and patient 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 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.
* Further updates will be available on the topic webpage in due course:

<https://www.nice.org.uk/guidance/indevelopment/gid-ta10829>

### Appraisal of zanubrutinib for treating waldenstrom's macroglobulinaemia [ID1427]

* 1. Part 1 – Open session
     1. The chair, Dr Jane Adam, welcomed the invited experts, external assessment group representatives, members of the public and company representatives from BeiGene
     2. The chair asked all committee members and experts, external assessment group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Prior to the meeting, Committee member Dominic Pivonka declared direct financial interests as his employer (AbbVie) has a treatment being evaluated in phase 2 studies for Waldenstrom’s macroglobulinaemia. AbbVie acquired the company which developed ibrutinib (available for people with previously-treated Waldenstrom’s macroglobulinaemia via the Cancer Drugs Fund) and markets ibrutinib in the United States. AbbVie does not market ibrutinib in Europe. It was agreed that his declarations would prevent Dominic Pivonka from participating in the committee discussions for this topic
  + Nominated Clinical expert Dr Shirley D’Sa declared direct and indirect financial interests as she has received a research support grant and advisory board fees from BeiGene and WMUK has received sponsorship from BeiGene towards the costs of the WMUK 2019 Patient / Doctor Summit. It was agreed that her declarations would not prevent Dr D’Sa from proving expert advice to the committee.
  + Nominated Clinical expert Dr Dima El-Sharkawi declared direct financial and non-financial interests as she has received advisory board and honoraria fees from AbbVie, AstraZeneca, Beigene, Janssen and Roche she is also a trustee of WMUK national charity. It was agreed that her declarations would not prevent Dr El-Sharkawi from proving expert advice to the committee.
    1. The Chair led a discussion of the consultation comments presented to the committee. This information was presented to the committee by the Chair.
  1. Part 2 – Closed session (company representatives, clinical and patient 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 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.
* Further updates will be available on the topic webpage in due course:

<https://www.nice.org.uk/guidance/indevelopment/gid-ta10705>

### Date of the next meeting

The next meeting of the Technology Appraisal Committee A will be held on Tuesday 12 July 2022 and will start promptly at 10:00am.