NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Technology Appraisal (Committee B) meeting minutes

 **Minutes:** Confirmed

**Date and time:** Thursday 4 March 2021, 9:30am – 18:02pm

**Location:** via Zoom

## Committee members present:

1. Professor Amanda Adler (Chair) Present for all items
2. Dr Sanjeev Patel (Vice Chair) Present for all items
3. Dr Carlo Berti Present for all items
4. Dr Laura Bojke Present for all items
5. Mr Mark Chapman Present for items 1 to 4
6. Professor Iolo Doull Present for all items
7. Dr Mark Glover Present for all items
8. Dr Megan John Present for all items
9. Dr Nicholas Latimer Present for all items
10. Dr Veline L’Esperance Present for all items
11. Dr Rhiannon Owen Present for all items
12. Ms Anna Pracz Present for all items
13. Mr Peter Wheatley Price Present for all items
14. Dr Stephen Smith Present for all items
15. Professor Nicky Welton Present for all items
16. Mr Nigel Westwood Present for all items
17. Professor Sarah Wild Present for items 1 to 4
18. Ms Mary Weatherstone Present for all items
19. Dr Stuart Williams Present for all items
20. Mr Tony Wootton Present for all items

## NICE staff present:

Nicole Elliott, Associate Director Present for items 1 to 4

Henry Edwards, Associate Director Present for items 5 and 6

Jo Ekeledo, Project Manager Present for items 1 to 4

Shonagh D’Sylva, Project Manager Present for items 5 and 6

Yelan Guo, Technical Advisor Present for items 1 to 4

Heather Stegenga, Technical Analyst Present for items 1 to 4

Carl Prescott, Technical Advisor Present for items 5 and 6

Aminata Thiam, Technical Analyst Present for items 5 and 6

Emilene Coventry, Senior Medical Editor Present for items 1 to 4

Ann Greenwood, Senior Medical Editor Present for items 5 and 6

Heidi Livingstone, Public Involvement Advisor Present for items 1 to 4.1.3. and 5.1

Philip Williams, Finance/Business Analyst Present for all items

Emily Eaton Turner, HTA Adviser Present for items 5 and 6

Ella Livingstone, Commercial Risk Present for item 5.1

Stevie Okoro, Commercial Risk Present for items 1 to 4

Catherine Pank, Assistant Project Manager Present for items 5 and 6

Mira Patel, Coordinator Present for all items

Victoria Hall, Coordinator Present for items 1 to 4.1.3. and 5.1

Rosalee Mason, Coordinator Present for items 1 to 4.1.3. and 5.1

Sophie McHugh, Administrator Present for all items

## External group representatives present:

Robert Wolff, Deputy Director, Kleijnen Systematic Reviews Present for items 1 to 4.2

Ben Wijnen, Health Economist, Kleijnen Systematic Reviews Present for items 1 to 4.2

Bram Ramaekers, Researcher, Kleijnen Systematic Reviews Present for items 1 to 4.2

Keith Cooper, Senior Research Fellow, Southampton Health Present for items 5.1 and 5.2

 Technology Assessments Centre

Jonathan Shepard, Principal Research Fellow, Southampton Present for items 5.1 and 5.2

 Health Technology Assessments Centre

Irina Tikhonova, Senior Research Fellow, Southampton Health Present for items 5.1 and 5.2

 Technology Assessments Centre

## Professional experts present:

Professor Helen Cross, clinical expert, The Prince of Present for items 1 to 4.1.3.

 Wales’s Chair of Childhood Epilepsy, UCL Great

 Ormond Street Hospital, nominated by Zogenix

Dr Sofia Eriksson, clinical expert, Consultant Neurologist, Present for items 1 to 4.1.3.

 nominated by Association of British Neurologists.

Ms Claire Eldred, patient expert, Chair of Trustees at Dravet Present for items 1 to 4.1.3.

 Syndrome UK, nominated by Dravet Syndrome UK

Ms Galia Wilson, patient expert, Head of Marketing and Present for items 1 to 4.1.3.

 Communications at Dravet Syndrome UK, nominated

 by Dravet Syndrome UK.

Professor Peter Clark, CDF Clinical Lead, NHSE&I Present for items 5 and 6

Dr Amit Bahl, clinical expert, Consultant Clinical Present for item 5.1

 Oncologist, University Hospitals Bristol, nominated by

 Janssen.

Dr Stephen Allen, patient expert, nominated by Tackle Present for item 5.1

 Prostate Cancer

Ms Rebecca Leszczynski, Senior Knowledge Officer at Present for item 5.1

 Prostate Cancer UK, nominated by Prostate Cancer UK

## Observers present:

Lorna Hazell, SHTAC Present for item 5.1 and 5.2

Steve Norton, Technical Analyst, Present for items 1 to 4.1.3.

Harsimran Sarpal, Technical Analyst Present for items 5 and 6

### 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 Ed Wilson.

### News and announcements

* 1. None.

### Minutes from the last meeting

* 1. The committee approved the minutes of the committee meetings held on 10 December 2020 and 4 February 2021.

### Appraisal of Fenfluramine for treating Dravet syndrome [ID1109]

* 1. Part 1 – Open session
		1. The chair welcomed the invited professional experts, external group representatives, members of the public and company representatives from Zogenix.
		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, Mr Mark Chapman, committee member, declared that his employer, Medtronic, manufacture deep brain stimulation which is a treatment for epilepsy. It is not a comparator. It was agreed that this declaration did not present a conflict of interest and did not prevent Mr Chapman from participating in this section of the meeting.

* Prior to the meeting, Mr Peter Wheatley-Price, committee member, declared that his employer, Takeda, had recently secured global rights to develop and commercialise soticlestat for the treatment of children and adults with Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS) from their partner Ovid Therapeutics. It was agreed that this declaration did not present a conflict of interest and did not prevent Mr Wheatley-Price from participating in this section of the meeting.
* In the meeting, Professor Helen Cross, clinical expert, declared direct non-financial interests as she is the Chair of the medical board of Dravet UK and was the lead investigator in clinical trials for Zogenix (RCT fenfluramine in Dravet syndrome), GW Pharma (RCTs Cannabidiol in Dravet and Lennox Gastaut syndromes) and Marinius (RCT Ganaxolone in CDKL5 deficiency), for which remuneration was made to her department. Professor Cross also declared direct financial interests as she attended an educational forum sponsored by Zogenix.

Prior to the meeting, Professor Cross declared direct non-financial interests as she is the Treasurer for Matthew’s Friends and President Elect for the International League Against Epilepsy*.* She was also the author of a review of fenfluramine in the press (an information piece). Professor Cross also declared financial interests as she contributed to two symposia on rare epilepsies/Dravet syndrome, at the British Paediatric Neurology Association meeting in January 2021, sponsored by educational grants from Biocodex and Zogenix. Renumeration was made to the BPNA and her department.

It was agreed that these declarations would not prevent Professor Cross from providing expert advice to the committee.

* Dr Sofia Eriksson, clinical expert, declared direct financial interests as she had received honoraria for educational activities and conference attendance from: UCB Pharma, Lincoln Pharma, Eisai and Fidia Pharma. These conferences were not related to the treatment being discussed. It was agreed that this declaration would not prevent Dr Eriksson from providing expert advice to the committee.
* Ms Claire Eldred, patient expert, declared an indirect interest as her employer, Dravet Syndrome UK, received unrestricted funding from pharmaceutical companies. It was agreed that this declaration would not prevent Claire from providing expert advice to the committee.
* Ms Galia Wilson, patient expert, declared an indirect interest as her employer, Dravet Syndrome UK, received unrestricted funding from pharmaceutical companies, including Zogenix, in recent years (within the ABPI Code of Practice). It was agreed that this declaration would not prevent Galia 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 Mark Glover, Mr Mark Chapman and Mr Tony Wootton, who gave presentations on the clinical effectiveness and cost effectiveness of Fenfluramine for treating Dravet syndrome [ID1109].
	1. Part 2a – Closed session (members of the public, company representatives and professional experts were asked to leave the meeting).
		1. The committee discussed confidential information submitted for this item.
	2. Part 2b – Closed session (external group representatives were asked to leave the meeting).
		1. The committee then agreed on the content of the Appraisal Consultation Document (ACD) or the 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 Apalutamide for treating prostate cancer [ID1534]

* 1. Part 1 – Open session
		1. The chair welcomed the invited professional experts, external group representatives, members of the public and company representatives from Janssen.
		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, Mr Peter Wheatley-Price, committee member, declared that his employer, Takeda, sells leuprorelin which is used in the hormonal stage of prostate cancer. It was agreed that this declaration did not present a conflict of interest and did not prevent Mr Wheatley-Price from participating in this section of the meeting.
* Dr Amit Bahl, clinical expert, declared direct financial interests as he had participated in paid advisory boards and received funding for meeting attendance and sponsorship from Sanofi, Astellas, BMS, Janssen, Pfizer, Bayer, EUSA. It was agreed that this declaration would not prevent Dr Bahl from providing expert advice to the committee.
* Dr Stephen Allen, patient expert, declared an indirect interest as Tackle Prostate Cancer receives funding from various pharmaceutical companies. Prior to the meeting, Dr Allen declared a direct financial interest as he received payment from Janssen, in the form of expenses, for him to attend a patient-centred conference in Europe. No commercial interests were involved. It was agreed that these declarations would not prevent Stephen from providing expert advice to the committee.
* Ms Rebecca Leszczynski, patient expert, declared an indirect interest as her employer, Prostate Cancer UK, receives funding from various pharmaceutical companies. It was agreed that this declaration would not prevent Rebecca from providing expert advice to the committee.

 No further conflicts of interest were declared for this item.

* + 1. The Chair introduced the lead team, Ms Anna Pracz, Dr Rhiannon Owen and Mr Nigel Westwood, who gave presentations on the clinical effectiveness and cost effectiveness of Apalutamide for treating prostate cancer [ID1534].
		2. The Chair then asked for the committee, NICE Staff and CDF clinical lead, Professor Peter Clark, to be moved to a closed private session in which confidential information was shared. The company representatives, professional experts, external group representatives and members of the public remained separate from this closed private session.
		3. All attendees were brought back together, and the lead team continued with presentations on the clinical effectiveness and cost effectiveness of Apalutamide for treating prostate cancer [ID1534].
	1. Part 2a – Closed session (members of the public, company representatives and professional experts were asked to leave the meeting).
		1. The committee discussed confidential information submitted for this item.
	2. Part 2b – Closed session (external group representatives were asked to leave the meeting).
		1. The committee then agreed on the content of the Appraisal Consultation Document (ACD) or the 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 B) will be held on Thursday 8 April 2021 and will start promptly at 9:30am.