**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

Centre for Health Technology Evaluation

# Technology Appraisal Committee C meeting minutes

**Minutes:** Confirmed

**Date:** Tuesday 13 April 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 David Foreman Present for items 3 to 4.2.2
6. Dr Robert Forsyth Present for all items
7. Dr Natalie Hallas Present for all items
8. John Hampson Present for all items
9. Dr Nigel Langford Present for all items
10. Iain McGowan Present for all items
11. Kirandip Moyo Present for items 1 to 2.2.2
12. Dr Richard Nicholas Present for all items
13. Ugochinyere Nwulu Present for all items
14. Stella O’Brien Present for all items
15. Professor Matthew Stevenson Present for items 1 to 3.2.2
16. Professor Paul Tappenden Present for all items
17. Dr Derek Ward Present for all items

## NICE staff present:

Jasdeep Hayre, Associate Director Present for items 1 to 2.2.2 & 4 to 4.2.2

Ross Dent, Associate Director Present for items 3 to 3.2.2

Gavin Kenny, Project Manager Present for items 1 to 2.2.2 & 4 to 4.2.2

Louise Jafferally, Project Manager Present for all items

Christian Griffiths, Health Technology Assessment Adviser Present for items 1 to 2.2.2

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

Nicola Hay, Health Technology Assessment Adviser Present for items 4 to 4.2.2

Anne Murray-Cota, Health Technology Assessment Analyst Present for items 1 to 2.2.2

Zain Hussain, Health Technology Assessment Analyst Present for items 3 to 3.2.2

Elizabeth Bell, Health Technology Assessment Analyst Present for items 3 to 3.2.2

Stephen Norton, Health Technology Assessment Analyst Present for items 4 to 4.2.2

Nigel Gumbleton, Health Technology Assessment Analyst Present for all items

Gareth Murphy, Business Analyst, RIA Present for all items

Ria Skelton, Senior Medical Editor Present for all items 1 to 3.2.2

Olivia Havercroft, Senior Medical Editor Present for items 4 to 4.2.2

Ella Livingstone, Technical Adviser, Commercial Risk Assessment, Present for items 1 to 2.2.2

Emily Eaton-Turner, Technical Adviser, Commercial Risk Assessment, Present for items 3 to 3.2.2

Claire Hawksworth, Technical Analyst, Evidence Generation, Present for items 3 to 3.2.2

Laura Marsden, Public Involvement Adviser, PIP, Present for items 1 to 2.1.3 & 4 to 4.1.3

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

Jonathan Simpson, Project Manager, CCT Present for items 4 to 4.2.2

Mira Patel, Coordinator, COT Present for items 4 to 4.2.2

Sandra Robinson, Coordinator, MIP Present for items 3 to 4.2.2

Gemma Smith, Coordinator, COT Present for all items

## External group representatives present:

Maiwenn Al, Kleijnen Reviews Ltd Present for items 1 to 2.1.3

Pim Wetzelaer, Kleijnen Reviews Ltd Present for items 1 to 2.1.3

Rob Riemsma, Kleijnen Reviews Ltd, Present for items 1 to 2.1.3

Marie Westwood, Kleijnen Reviews Ltd Present for items 3 to 3.1.3

Hannah Penton, Kleijnen Reviews Ltd Present for items 3 to 3.1.3

Alexis Llewellyn, NHS Centre for Reviews & Dissemination & Centre for Health Economics – York, Present for items 4 to 4.1.3

Claire Rothery, NHS Centre for Reviews & Dissemination & Centre for Health Economics – York, Present for items 4 to 4.1.3

## Clinical & Patient experts present:

Dr Sonya Craig, Consultant Sleep and Respiratory Physician, clinical expert, nominated by the British Thoracic Society, Present for items 1 to 2.1.3  
  
Graham Hill, patient expert, nominated by the Sleep Apnoea Trust Association, Present for items 1 to 2.1.3

Dr Ari Manuel, Consultant in sleep medicine, clinical expert, nominated by Lincoln Medical, Present for items 1 to 2.1.3

Dr Chiara Braconi, Consultant Medical Oncologist, clinical expert nominated by Cholangiocarcinoma-UK and the National Cancer Research Institute-Association of Cancer Physicians-Royal College of Physicians-Royal College of Radiologists, Present for items 3 to 3.1.3

Professor Peter Clark, CDF Clinical Lead, NHS England, Present for items 3 to 3.2.2

Professor Maria Hawkins, Professor in Radiation Oncology/Honorary Consultant in Clinical Oncology, clinical expert, nominated by Cholangiocarcinoma-UK, Present for items 3 to 3.1.3

Helen Morement, Patient expert, nominated by AMMF – The Cholangiocarcinoma Charity and Cholangiocarcinoma-UK, Present for items 3 to 3.1.3

Andrea Sheardown, Patient expert, nominated by AMMF – The Cholangiocarcinoma Charity, Present for items 3 to 3.1.3

Professor David Kavanagh, Clinical expert, nominated by Alexion Pharma UK, Present for items 4 to 4.1.3

Fiona Marley, Head of Specialised Commissioning, NHS England, Present for items 4 to 4.1.3

Christopher Reardon, Patient expert, nominated by aHUS alliance Global Action, Present for items 4 to 4.1.3

Dr Edwin Wong, Consultant nephrologist, clinical expert, nominated by the National Renal Complement Therapeutics Centre, Present for items 4 to 4.1.3

Len Woodward, Patient expert, nominated by aHUS alliance Global Action, Present for items 4 to 4.1.3

### 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 pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea [ID1065]

* 1. Part 1 – Open session
     1. The chair welcomed the invited clinical & patient experts, external group representatives & company representatives from Lincoln Medical.
     2. The chair asked all committee members, clinical & 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 provided consultancy advice to Shire Pharmaceuticals in disease areas in an unrelated area, most recently in late 2017. Shire is now part of Takeda Pharmaceuticals, with whom I currently have a long-term contract to undertake activities in EU Innovative Medicines Initiative [IMI] projects, again in an unrelated area of this appraisal.
* It was agreed that his declaration would not prevent Mr Chambers from participating in this section of the meeting.
* Dr Richard Nicholas declared financial interests as he has been paid advisory boards for Novartis for treatments 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 Sonya Craig declared non-financial interests as she is sitting on an advisory board for pitolisant which is another drug for excessive daytime sleepiness and has attended the ERS conference in Madrid 2019 paid for by Bioprojet who make pitolisant, she confirmed she had received no payment.
* It was agreed that her declaration would not prevent Dr Craig from providing expert advice to the committee.
* Dr Ari Manuel declared a financial interest as he has provided a lecture for Lincoln Medical on the pathophysiology of OSA in April 2020 and was paid £400.
* It was agreed that his declaration would not prevent Dr Manuel from providing expert advice to the committee.
* No further conflicts were declared for this item.
  + 1. The Chair introduced the lead team Dr Nigel Langford, Kirandip Moyo and Ugochi Nwulu who gave presentations on the clinical effectiveness and cost effectiveness of pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea.
  1. Part 2 – Closed session [company representatives, clinical & patient experts & external group representatives 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 pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 alterations [ID3740]

* 1. Part 1 – Open session
     1. The chair Professor Steve O’Brien welcomed the invited clinical & patient experts, external group representatives, members of the public and company representatives from Incyte.
     2. The chair asked all committee members, clinical & patient experts, external 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 this item.
  + 1. The Chair introduced the lead team John Hampson, Ugochi Nwulu who would be joining him, in giving presentations on the clinical effectiveness and cost effectiveness of pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 alterations.
  1. Part 2 – Closed session [company representatives, clinical & 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 ravulizumab for treating atypical haemolytic uraemic syndrome - aHUS [ID1530]

* 1. Part 1 – Open session
     1. The chair Dr Peter Selby welcomed the invited clinical & patient experts, external group representatives, members of the public and company representatives from Alexion.
     2. The chair asked all committee members, clinical & patient experts, external group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Professor Paul Tappenden declared non-financial professional & personal interests as he is an unpaid member of a trial steering committee for the NIHR-funded SETSaHUS study which is looking at the safety of abrupt withdrawal of eculizumab in patients with aHUS.
* It was agreed that his declaration would not prevent Professor Tappenden from participating in this section of the meeting.
* Len Woodward declared financial interests as he has received honoraria fees and travel expenses from Alexion for participating as a patient advocate on its aHUS Registry Scientific Advisory Board [2/2015 -12/2019] and for talks to the Alexion employees and UK investigators about the Global aHUS Patients’ research agenda.
* It was agreed that his declaration would not prevent Mr Woodward from providing expert advice to the committee.
* Dr Edwin Wong declared financial interests as he has received payments for contributions to advisory boards & speaking engagements on behalf of Alexion, Biocryst and Novartis, is a member of a study team in a clinical trial of published apprasal ravulizumab in atypical haemolytic uraemic syndrome, he was also local principal investigator in a clinical trial of eculizumab withdrawal in patients with atypical haemolytic uraemic syndrome - ISRCTN17503205 – trial ongoing.
* It was agreed that his declaration would not prevent Dr Wong from providing expert advice to the committee.
* Professor David Kavanagh declared financial interests as he has received honoraria for consultancy work from Alexion and received advisory board payments from Idorsia, Novartis, ChemoCentryx, Apellis, Biomarin and Sarepta, he is director and scientific advisor to Gyroscope Therapeutics and has a patent pending. [patent reference: P030973GB complement factor I] he also noted that his spouse works for GSK.
* It was agreed that his declarations would not prevent Professor Kavanagh from providing expert advice to the committee
* Dr Prithwiraj Das had noted pre-meeting that discussions on the AZ acquisition of Alexion are progressing in the background - it was agreed that as its acquisition has been announced, as a direct financial conflict Dr Das will not be participating in discussions on this appraisal.
* Professor Matthew Stevenson had noted pre-meeting that he had provided advice, for a fee to Alexion in relation to ravulizumab for the treatment of PNH. As this is a direct financial conflict Professor Stevenson will not be participating in discussion on this appraisal.
* No further conflicts of interest were declared for this item.

* + 1. The Chair introduced the lead team Michael Chambers, Dr Robert Forsyth and Ugochi Nwulu, who gave presentations on the clinical effectiveness and cost effectiveness of ravulizumab for treating atypical haemolytic uraemic syndrome.
  1. Part 2 – Closed session [company representatives, clinical & 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.

1. Date of the next meeting

The next meeting of the Technology Appraisal (Committee C) will be held on Tuesday 11 May 2021 and will start promptly at 9.30am.