Technology Appraisal Virtual Committee Meeting

# Committee C

# Minutes: Confirmed

## Date and Time: Thursday 5 November 2020 at 9:30am (Held via Zoom)

## Present:

* Alex Cale Present for all notes
* Michael Chambers Present for all notes
* Prithwiraj Das Present for all notes
* David Foreman Present for all notes
* Rob Forsyth Present for all notes
* Natalie Hallas Present for all notes
* John Hampson Present for all notes
* Nigel Langford Present for all notes
* Andrea Manca Present for all notes
* Iain McGowan Present for all notes
* Richard Nicholas Present for all notes
* Stella O'Brien Present for all notes
* Stephen O’Brien (C) Present for all notes
* Subhash Pokhrel Present for all notes
* Andrew Renehan Present for notes 1 to 9
* Peter Selby (C) Present for all notes
* Matthew Stevenson Present for notes 1 to 17
* Paul Tappenden Present for notes 10 to 25
* Derek Ward Present for all notes

## NICE Staff In attendance:

* Ross Dent, Associate Director, NICE, Present for notes1 to 9 & 18 to 25
* Jasdeep Hayre, Associate Director, NICE, Present for notes 10 to 17
* Louise Jafferally, Project Manager, NICE, Present for all notes
* Kate Moore, Project Manager, NICE, Present for all notes
* Gavin Kenny, Project Manager, NICE, Present for all notes
* Richard Diaz, Technical Adviser, NICE, Present for notes 1 to 9
* Jamie Elvidge, Technical Adviser, NICE, Present for notes 18 to 25
* Victoria Kelly, Technical Adviser, NICE, Present for notes 10 to 17
* Cameron Collins, Technical Analyst, NICE, Present for notes 10 to 17
* Omar Moreea, Technical Analyst, NICE, Present for notes 1 to 9
* Abi Senthinathan, Technical Analyst, NICE, Present for notes 18 to 25
* Catherine Pank, Corporate Office Coordinator, NICE, Present for all notes 1 to 5 & 10 to 14
* Gemma Smith, Committee Operations Coordinator, NICE, Present for all notes
* Mandy Tonkinson, Public Involvement Adviser, NICE. Present for notes 1 to 9
* Ismahan Abdullah, Technology Appraisals Administrator, NICE, Present for notes 10 to 17
* Sophie McHugh, Committee Operations Administrator, NICE Present for notes 1 to 17

## ERG Representatives in attendance:

* Aline Navega Biz, ScHARR, Evidence Review Group, Present for notes 1 to 6
* Paul Tappenden, ScHARR, Evidence Review Group, Present for notes 1 to 6
* Gemma Marceniuk, BMJ Group, Evidence Review Group, Present for notes 10 to 14
* Victoria Wakefield, BMJ Group, Evidence Review Group, Present for notes 10 to 14
* Andrew Metry, ScHARR, Evidence Review Group, Present for notes 18 to 22
* John Stevens, ScHARR, Evidence Review Group, Present for notes 18 to 22
* Matt Stevenson, ScHARR, Evidence Review Group, Present for notes 18 to 22

## Clinical & Patient experts in attendance:

* Adrian Bloor, Clinical Expert, Consultant Haematologist, Present for notes 1 to 5
* Prof Peter Clark, Cancer Drugs Fund Clinical Lead, Present for notes 1 to 9 & 18 to 25
* Anna Schuh, Clinical Expert, Associate Professor and Consultant

Haematologist, Present for notes 1 to 5

* Kathryn Ryan, Clinical Expert, Consultant Chemical Pathologist, Present for notes 10 to 14
* Jackie Martin, Patient Expert, Advocacy Officer, Present for notes 1 to 5

Nick York, Patient Expert,

Patient Advocacy and Healthcare Liaison

* Officer, Present for notes 1 to 5
* Simon Williams, Patient Expert, Head of Communications & Policy, Heart UK, Present for notes 10 to 14

## Other Non-public attendees:

* Sarah Bromley, Editor, NICE, Present for notes 10 to 25
* Ann Greenwood, Editor, NICE, Present for notes 1 to 9
* Christian Griffiths, HTA Adviser, NICE, Present for notes 18 to 25
* Tomas Keating, HTA Analyst, NICE, Present for all notes
* Emily Leckenby, HTA Analyst, NICE, Present for all notes
* Ella Livingstone, Technical Adviser, Commercial Risk Assessment, NICE, Present for all notes
* Alan Moore, HTA Analyst, NICE, Present for notes 10 to 17
* Gareth Murphy, Business Analyst, NICE, Present for all notes
* Anne Murray-Cota, HTA Analyst, NICE, Present for notes 1 to 17

Stevie Okoro, Technical Analyst, Commercial Risk Assessment, NICE, Present for notes 1 to 9 & 18 to 25

### Appraisal of Acalabrutinib for untreated and treated chronic lymphocytic leukaemia (ID1613)

### Part 1 – Open session

1. The Chair welcomed the invited clinical and patient experts, Evidence Review Group (ERG) representatives and representatives from AstraZeneca.
2. The Chair asked all committee members, experts, ERG representatives and NICE staff present to declare any relevant interests:  
   1. Michael Chambers declared a financial interest as he is currently helping to co-ordinate a training programme on Real World Evidence for Roche pharmaceuticals however this has not involved specific consideration of any Roche products.
      1. It was agreed that this declaration would not prevent Michael from participating in discussion on this topic.
   2. Prithwiraj Das declared a non-financial & personal Interest as he works at Boehringer Ingelheim Ltd as the Market Access Lead on Specialty Medicines (oncology, inflammation, thrombolysis). However, he has not worked on any of these indications in the last 12 months.
      1. It was agreed that this declaration would not prevent Prithwiraj from participating in discussions on this topic.
   3. Richard Nicholas declared a non-financial & personal Interest as he was on advisory boards and was PI on trials for Roche and Novartis regarding Multiple Sclerosis.
      1. It was agreed that this declaration would not prevent Richard from participating in this section of the meeting.
   4. Matthew Stevenson declared non-financial professional & personal Interest as ScHARR is the ERG for this topic, however, he was not involved in this report.
      1. It was agreed that this declaration would not prevent Matthew from participating in discussions on this topic
   5. Adrian Bloor declared a direct financial Interest as he has attended advisory boards and has received conference funding and speaker funding for Novartis, Gilead, Abbvie and Janssen in the last 5 years and is the medical lead for the Doctors Laboratory Manchester Hub.
      1. It was agreed that this declaration would not prevent Adrian from participating in this section of the meeting.
   6. Anna Schuh declared both direct and non-direct financial Interests as she has received honoraria for giving education talks from Abbvie, Roche, Janssen and Gilead in the last two years, and is a PI on the Abbvie study M13-982 which was the study evaluating venetoclax in patients with del17 CLL.
      1. It was agreed that this declaration would not prevent Anna from participating in this section of the meeting.
   7. Nick York declared both direct and non-direct financial Interests as he is an employee of Leukaemia Care and Chair of the CLL Advocates Network (CLLAN), which also receives funding from pharmaceutical companies.
      1. It was agreed that this declaration would not prevent Nick from participating in this section of the meeting.
   8. Jackie Martin declared both direct and non-direct financial interests as a patient with CLL undergoing treatment with Ibrutinib as a participant in the FLAIR clinical trial. She is also an administrator for the online CLL patient forum on the Health Unlocked platform and a patient advocate which also receive funding from pharmaceutical companies.
      1. It was agreed that this declaration would not prevent Jackie from participating in this section of the meeting.
3. No further conflicts of interest were declared for this appraisal.
4. The Chair introduced the lead team who gave presentations on the clinical effectiveness and cost effectiveness of the treatment.
5. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

### Part 2a – Closed session (company representatives, clinical and patient experts and members of the public were asked to leave the meeting)

1. The committee discussed confidential information submitted as part of this appraisal.

### Part 2b – Closed session (ERG representatives were asked to leave the meeting)

1. Agreement on the content of the Appraisal Consultation Document (ACD) was discussed by the committee.
2. The committee decision was based on consensus.
3. The committee asked the NICE technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

### Appraisal of Bempedoic acid for treating primary hypercholesterolaemia or mixed dyslipidaemia (ID1515)

### Part 1 – Open session

1. The Chair welcomed the invited clinical and patient experts, Evidence Review Group (ERG) representatives and representatives from Daiichi Sankyo.
2. The Chair asked all committee members, experts, ERG representatives and NICE staff present to declare any relevant interests  
   1. Prithwiraj Das declared a non-financial & personal Interest as he works at Boehringer Ingelheim Ltd as the Market Access Lead on Specialty Medicines (oncology, inflammation, thrombolysis). However, he has not worked on any of these indications in the last 12 months.
   2. It was agreed that this declaration would not prevent Prithwiraj from participating in this section of the meeting.
   3. Richard Nicholas declared a non-financial & personal Interest as he was on advisory boards and was PI on trials for Roche and Novartis regarding Multiple Sclerosis.
      1. It was agreed that this declaration would not prevent Richard from participating in this section of the meeting.
   4. Simon Williams declared a non-financial & personal Interest as he works for Heart UK who receive of which Daichii Sankyo, Sanofi and Amgen are members of the HEART UK Collaborative Group and pay an annual fee.
      1. It was agreed that this declaration would not prevent Simon from participating in this section of the meeting.
3. No further conflicts of interest were declared for this appraisal.
4. The Chair introduced the key themes arising from the consultation responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.
5. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy before opening discussions.

### Part 2 – Closed session (company representatives, clinical and patient experts, ERG/AG representatives and members of the public were asked to leave the meeting)

1. Agreement on the content of the Appraisal Consultation Document (ACD) was discussed by the committee.
2. The committee decision was based on consensus.
3. The committee asked the NICE technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

### Appraisal of Trifluridine–tipiracil for treating metastatic gastric or gastro-oesophageal junction cancer after 2 or more therapies (ID1507)

### Part 2a – Closed session

1. The Chair welcomed the CDF Expert, Evidence Review Group (ERG) representatives and representatives from Servier Laboratories.
2. The Chair asked all committee members, experts, ERG representatives and NICE staff present to declare any relevant interests  
   1. Prithwiraj Das declared a non-financial & personal Interest as he works at Boehringer Ingelheim Ltd as the Market Access Lead on Specialty Medicines (oncology, inflammation, thrombolysis). However, he has not worked on any of these indications in the last 12 months.
      1. It was agreed that this declaration would not prevent Prithwiraj from participating in this section of the meeting
   2. Paul Tappenden declared a non-financial professional & personal Interest as he had provided peer review comments on the draft version of the ERG report.
      1. It was agreed that this declaration would not prevent Paul from participating in this section of the meeting.
3. No further conflicts of interest were declared for this appraisal.
4. The Chair introduced the key themes arising from the consultation responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.
5. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy before opening discussions.

### Part 2b – Closed session (company representatives and ERG representatives were asked to leave the meeting)

1. Agreement on the content of the Final Appraisal Determination (FAD) was discussed by the committee.
2. A vote was taken. The options were:  
   Option 1: The End of Life criteria has been met.  
   Option 2: The End of Life criteria has not been met  
   The committee voted for Option 2.
3. The committee asked the NICE technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.