NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Technology Appraisal (Committee B) meeting minutes

**Minutes:** Confirmed

**Date and time:** Thursday 8 April 2021, 9:30am – 17:18pm

**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. Mr Mark Chapman Present for items 1 to 5
5. Professor Iolo Doull Present for all items
6. Dr James Fotheringham Present for all items
7. Dr Mark Glover Present for all items
8. Dr Megan John Present for items 1 to 7.1.3.
9. Dr Nicholas Latimer Present for all items
10. Dr Veline L’Esperance Present for all items
11. Dr Rhiannon Owen Present for items 7 and 8
12. Ms Anna Pracz Present for all items
13. Mr Peter Wheatley Price Present for all items
14. Dr Stephen Smith Present for items 1 to 4
15. Professor Nicky Welton Present for all items
16. Mr Nigel Westwood Present for all items
17. Professor Sarah Wild Present for all items
18. Ms Mary Weatherstone Present for all items
19. Dr Stuart Williams Present for all items
20. Dr Ed Wilson Present for all items
21. Mr Tony Wootton Present for all items

## NICE staff present:

Nicole Elliott, Associate Director Present for all items

Henry Edwards, Associate Director Present for items 5 to 8

Ross Dent, Associate Director Present for item 6

Jo Ekeledo, Project Manager Present for items 1 to 4 and 6

Shonagh D’Sylva, Project Manager Present for items 5 to 8

Lorna Dunning, Technical Advisor Present for items 1 to 4

Emma Douch, Technical Analyst Present for items 1 to 4

Hannah Nicholas, Technical Advisor Present for item 5

Emily Leckenby, Technical Analyst Present for item 6

Carl Prescott, Technical Advisor Present for items 7 and 8

Aminata Thiam, Technical Analyst Present for items 7 and 8

Benjamin Pearce, Senior Medical Editor Present for items 1 to 4

Ann Greenwood, Senior Medical Editor Present for items 5 to 8

Helen Barnett, Senior Medical Editor Present for item 6

Laura Marsden, Public Involvement Advisor Present for items 1 to 4

Edgar Masanga, Business Analyst, RIA Present for all items

Emily Eaton Turner, HTA Adviser Present for items 5 to 8

Ella Livingstone, Commercial Risk Present for items 5 to 8

Stevie Okoro, Commercial Risk Present for items 1 to 4

Catherine Pank, Assistant Project Manager Present for items 5 to 8

Ian Wall, Assistant Project Manager Present for items 5 to 7.1.2.

Mira Patel, Coordinator Present for all items

Victoria Hall, Coordinator Present for items 1 to 4.1 and 5.1

Rosalee Mason, Coordinator Present for items 1 to 4.1 and 5.1

Sophie McHugh, Administrator Present for items 1 to 4 and 6

Daniel Greenwood, Assistant Administrator Present for item 5 to 8

## External group representatives present:

Samantha Barton, Principal HTA Analyst, BMJ-TAG Present for items 1 to 4.2

Tracey Jhita, Health Economics Manager, BMJ-TAG Present for items 1 to 4.2

James Mahon, Health Economist, Liverpool Reviews and Present for items 5.1 and 5.2

Implementation Group

Nigel Fleeman, Research Fellow, Liverpool Reviews and Present for items 5.1 and 5.2

Implementation Group

## Professional experts present:

Professor Peter Clark, CDF Clinical Lead, NHSE&I Present for items 1 to 4 and 6 to 8

Dr Kai-Keen Shui, clinical expert, Consultant Medical Oncologist, Present for items 1 to 4.1

University College London Hospitals NHS Foundation Trust,

nominated by Merck Sharp & Dohme

Professor Mark Saunders, clinical expert, Consultant Clinical Present for items 1 to 4.1

Oncologist, Christie NHS Foundation, nominated by Bowel

Cancer UK

Ms Hayley Crawley, patient expert, nominated by Bowel Cancer UK Present for items 1 to 4.1

Mr Momenul Haque, patient expert, nominated by Bowel Cancer UK Present for items 1 to 4.1

Dr Eli Siber, clinical expert, Consultant Neurologist, Present for item 5.1

Kings College Hospital, nominated by MS Trust

Dr Victoria Williams, clinical expert, Consultant Neurologist, Present for item 5.1

Guy’s and St Thomas’ NHS Trust, nominated by

Association of British Neurologists

## Observers present:

Nithya Ajith, Medical Editor, NICE Present for item 5.1

Elizabeth Bell, Technical Analyst, NICE Present for items 1 to 4

Adam Brooke, HTA Advisor, NICE Present for items 1 to 4

Jennifer Hacking, Medical Editor, NICE Present for item 5

Summaya Mohammed, Technical Analyst, NICE Present for all items

Catherine Parker, Technical Analyst, NICE Present for items 1 to 4

Harsimran Sarpal, Technical Analyst, NICE Present for items 1 to 4

### 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 Laura Bojke and Dr Toby Smith.

### News and announcements

* 1. None.

### Minutes from the last meeting

* 1. The committee approved the minutes of the committee meetings held on 4 March 2021.

### Appraisal of Pembrolizumab for untreated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1498]

* 1. Part 1 – Open session
     1. The Chair welcomed the invited professional experts, external group representatives, members of the public and company representatives from MSD.
     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 Nicholas Latimer, committee member, declared a direct financial interest as he received payment by Merck Serono to present methods for modelling treatment sequences at ISPOR Webinar. The presentation was unrelated to any specific drug or disease area. Dr Latimer also declared a direct non-financial interest as he currently has a data sharing agreement with Amgen, manufacturer of a comparator drug. This agreement involves conducting methodological research analysing data from old studies of panitumumab in colorectal cancer. No payment is received by Dr Latimer or his institution. It was agreed that these declarations did not prevent Dr Latimer from participating in this section of the meeting.
* Professor Mark Saunders, clinical expert, declared direct financial interests as in the last 3 years, he had been paid to chair meetings and/or lecture by Servier, Merck Serono and Amgen*.* Professor Saunders also declared non-financial professional and personal interests as he the Chair of Bowel Cancer UK’s Medical Advisory Board. It was agreed that these declarations would not prevent Professor Saunders from providing expert advice to the committee.
* Dr Kai-Keen Shui, clinical expert, declared several direct financial interests as received consultancy fees and partook in paid advisory boards for MSD and Roche. Dr Shui is on the Council and paid advisory board for Mirati Therapeutics. Dr Shui has also received honoraria for educational talks to oncologists about managing CRC and UGI cancers from: MSD, Merck KGaA and Daiiichi-Sankyo, BMS, Guardant Health and Roche. Dr Shui also declared indirect interests as he is Chief Investigator for:

1) KEYNOTE 177 trial, April 2016 -

2) KEYNOTE 859 and KEYNOTE 811 (pembrolizumab metastatic gastric trials)

3) upcoming MSD investigator led/UCL sponsored trial - NEOPRISM-CRC - of neo-adjuvant pembrolizumab for operable MMR-d/MSI-H colorectal cancer.

In all instances, the trials are ongoing and all monies go to UCLH or UCL. Dr Shui also declared a further indirect interest as he is the co-author on ASCO 2020 Abstract and two papers relating to KEYNOTE 177. Finally, Dr Shui declared that his institution received research grants from: MSD, Roche, BMS, Gilead and Merck Serono. It was agreed that these declarations would not prevent Dr Shui 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 Sanjeev Patel, Mr Peter Wheatley-Price and Mr Tony Wootton, who gave presentations on the clinical effectiveness and cost effectiveness of Pembrolizumab for untreated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1498].
  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 Ozanimod for treating relapsing-remitting multiple sclerosis [ID1294]

* 1. Part 1 – Open session
     1. The Vice Chair welcomed the invited professional experts, external group representatives, members of the public and company representatives from Celgene/Bristol-Myers Squibb.
     2. The Vice 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 Nicholas Latimer, committee member, declared a direct financial interest as he received payment by Merck Serono to present methods for modelling treatment sequences at ISPOR Webinar. The presentation was unrelated to any specific drug or disease area. It was agreed that this declaration did not prevent Dr Latimer from participating in this section of the meeting.
* Prior to the meeting, Dr James Fotheringham, committee member, declared a direct financial interest as he received speaker fees from Novartis for chairing an industry symposium. Dr Fotheringham also declared an indirect interest as his employer, University of Sheffield, received funding from Novartis to author a NICE Briefing Book to inform a NICE Scientific Advisory meeting. Both declarations relate to kidney transplantation. It was agreed that these declarations did not prevent Dr Fotheringham from participating in this section of the meeting.
* Prior to the meeting, Dr Eli Silber, clinical expert, declared an indirect interest as his employer, King’s College Hospital, received funding for participating in trials of this drug. Dr Silber derived no personal benefit from any of the work undertaken. It was agreed that this declaration would not prevent Dr Silber from providing expert advice to the committee.
* No further conflicts of interest were declared for this item.
  + 1. The Vice 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.
  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.

1. Appraisal of Enzalutamide with androgen deprivation therapy for treating metastatic hormone-sensitive prostate cancer [ID1605]
   1. Part 2 – Closed session (members of the public, company representatives, external group representatives and professional experts were not present at this meeting).

6.1.1. The Chair asked all committee members and NICE staff present to declare any relevant interests.

* Prior to the meeting, Dr Nicholas Latimer, committee member, declared a direct financial interest as he received payment by Ferring to provide economic modelling advice on rebyota for clostridium difficile infection, in May 2020. Ferring manufacture a comparator drug. It was agreed that this declaration did not prevent Dr Latimer from participating in this section of the meeting.
* Prior to the meeting, Mr Peter Wheatley-Price, committee member, declared a direct financial interest as his employer, Takeda, manufacture Prostap/Prostap DCS (leuprorelin acetate) which is listed as a comparator drug. It was agreed that this declaration did not prevent Mr Wheatley-Price from participating in this section of the meeting.

6.1.2. The Chair gave a presentation on the clinical and cost effectiveness of Enzalutamide with androgen deprivation therapy for treating metastatic hormone-sensitive prostate cancer [ID1605].

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

6.1.4. 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.

6.1.5. 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. Appraisal of Apalutamide for treating prostate cancer [ID1534]
   1. Part 2 – Closed session (members of the public, company representatives, external group representatives and professional experts were not present at this meeting).

7.1.1. The Chair asked all committee members and NICE staff present to declare any relevant interests.

* 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 prevent Mr Wheatley-Price from participating in this section of the meeting.

7.1.2. The Chair gave a presentation on the clinical and cost effectiveness of Apalutamide for treating prostate cancer [ID1534].

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

7.1.4. 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.

7.1.5. 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 Wednesday 5 May 2021 and will start promptly at 9:30am.