NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Technology Appraisal Committee B meeting minutes

**Minutes:** Confirmed

**Date:** Thursday 12 January 2023, 9:30am

**Location:** Via Zoom

## Attendees

Committee members present

1. Dr Charles Crawley (Chair) Present for all items
2. Baljit Singh (Vice-chair) Items 5 to 6.2.2
3. Professor Iolo Doull Items 1 to 6.1.3
4. Professor Francis Drobniewski Present for all items
5. Dr Bushra Hasnie Present for all items
6. Dr Veline L’Esperance Present for all items
7. Dr Warren Linley (Observer) Present for all items
8. Professor David McAllister Present for all items
9. Dr Alistair Patton (Observer) Items 1 to 4.3.2
10. Anna Pracz Present for all items
11. Gabriel Rogers  Present for all items
12. Dr Toby Smith Items 1 to 5.2.2
13. Professor Nicky Welton Items 5 to 6.2.2
14. Nigel Westwood Present for all items
15. Tony Wootton Present for all items
16. Carole Pitkeathley Items 5 to 6.2.2
17. Dr James Fotheringham Items 6 to 6.2.2
18. Malcolm Oswald Items 6 to 6.2.2
19. Steve Edwards Items 1 to 4.3.2

NICE staff (key players) present

Henry Edwards, Associate Director Items 1 to 4.3.2

Janet Robertson, Associate Director Items 5 to 5.2.2

Richard Diaz, Associate Director Items 6 to 6.2.2

Jeremy Powell, Project Manager Items 1 to 4.3.2

Thomas Feist, Project Manager Items 5 to 5.2.2

Daniel Davies, Project Manager Items 6 to 6.2.2

Fatima Chunara, Health Technology Assessment Adviser Items 1 to 4.3.2

Ross Wilkinson, Health Technology Assessment Analyst Items 1 to 4.3.2

Ivan Maslyankov, Health Technology Assessment Analyst Items 1 to 4.3.2

Philip Williams, Business Analyst, RIA Present for all items

Anna Sparshatt, Senior Medical Editor Items 1 to 4.3.2

Helen Barnett, Senior Medical Editor Items 5 to 5.2.2

Laura Marsden, Public Involvement Adviser, PIP Items 1 to 4.3.2

Ella Fitzpatrick, Public Involvement Adviser, PIP Items 5 to 5.2.2

Emma Gordon, Coordinator, MIP Items 1 to 4.3.2 & 6 to 6.2.2

Rosalee Mason, Coordinator, MIP Items 5 to 5.2.2

Carl Jackson, Assistant Project Manager, COT Present for all items

Denise Moyo, Coordinator, COT Present for all items

Rumana Zaman, Administrator, TA Items 1 to 4.3.2

Marcia Miller, Administrator, TA Items 5 to 5.2.2

Wajeeha Asim, Administrator Items 6 to 6.2.2

NICE staff (observers) present

Catrin Austin, Technical Analyst, Managed Access Items 1 to 4.3.2

Emily Eaton-Turner, Technical Analyst, Commercial Liaison Team Items 1 to 5.2.2

Sarah Wilkes, Technical Analyst, TA Items 1 to 5.2.2

External assessment group representatives present

Nicky Welton, Bristol Technology Assessment Group (Bristol TAG), University of Bristol, Items 1 to 4.2.1

Deborah Caldwell, Bristol Technology Assessment Group (Bristol TAG), University of Bristol, Items 1 to 4.2.1

Kate Ren, School of Health and Related Research (ScHARR), Items 5 to 5.1.3

Sarah Davis, School of Health and Related Research (ScHARR), Items 5 to 5.1.3

G.J. Melendez-Torres, Peninsula Technology Assessment Group (Pen-TAG), Items 6 to 6.1.3

Clinical, Patient & NHS England experts present

Professor Gordon Cook, Professor of Haematology & Hon Consultant, clinical expert nominated by Janssen, Items 1 to 4.2.1

Dr Neil Rabin, Consultant Haematologist, clinical expert nominated by UK Myeloma Forum, Items 1 to 4.2.1

Rosie Dill, patient expert nominated by Myeloma UK, Items 1 to 4.2.1

Shelagh McKinlay, Director of Research and Advocacy, patient expert nominated by Myeloma UK, Items 1 to 4.2.1

Professor Peter Clark, Cancer Drug Fund Clinical Lead, NHS England, Items 1 to 5.2.2

Peter Isard, Patient, patient expert nominated by Tackle Prostate Cancer, Items 5 to 5.1.3

Professor Amit Bahl, Consultant Oncologist, clinical expert nominated by Novartis, Items 5 to 5.1.3

Dr Amarnath Challapalli, Consultant Oncologist, clinical expert nominated by Prostate Cancer UK, Items 5 to 5.1.3

Sabina Dizdarevic, Research Lead, clinical expert nominated by British Nuclear Medicine Society and Items 5 to 5.1.3

Dr Stephen Allen, Patient Representative and current Acting Chairman, patient expert nominated by Tackle Prostate Cancer, Items 5 to 5.1.3

Kieran McCafferty, Consultant Nephrologist, clinical expert nominated by Barts Health NHS Trust, Items 6 to 6.1.3

Stephen Bain, Professor of Medicine (Diabetes), clinical expert nominated by Swansea University Medical School, Items 6 to 6.1.3

## Minutes

### 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 Hatim Abdulhussein, Maria Bretzitski, Dr Mark Glover, Mary Weatherstone, Peter Wheatley-Price, Dr Rhiannon Owen, Dr Stuart Williams.

### News and announcements

* 1. None

### Minutes from the last meeting

* 1. The committee approved the minutes of the committee meeting held on Wednesday 14 December 2022.

1. **Appraisal of Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma when stem cell transplant is unsuitable [ID4014]**
   1. Part 1 – Open session
      1. The chair welcomed the invited experts, external assessment group representatives, members of the public and company representatives from Janssen.
      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.

* Dr Charles Crawley declared a non-financial professional and personal interest as he treats patients with Myeloma in his NHS practice. It was agreed that his declaration would not prevent Dr Charles Crawley from participating in discussions on this appraisal.
* Prior to the meeting, Professor David McAllister declared a non-financial professional and personal interest as he conducts academic research using individual-level participant data provided by the sponsors ad/or their competitors. The data is accessed via trial data sharing platforms (such as Vivli). It was agreed that his declaration would not prevent Professor David McAllister from participating in discussions on this appraisal.
* Shelagh McKinlay declared an indirect financial interest as Myeloma UK receives funding from Celgene, Bristol Myers-Squibb, and Janssen-Cilag for a range of purposes and activities namely core grants, project specific work including clinical trials, and gifts, honoraria or sponsorship. It was agreed that her declaration would not prevent Shelagh McKinlay from providing expert advice to the committee.
* Professor Gordon Cook declared a non-financial professional and personal interest as he is a Myeloma specialist and has advised NHS England on BMT, CRG and chemotherapy CRG and the implementation of cartridges in myeloma. He also receives consultancy from BMS/Celgene, Takeda, Janssen, Sanofi, Roche, Amgen, Oncopeptides, Karyopharm, Abbvie, Pfizer. It was agreed that his declaration would not prevent Professor Gordon Cook from providing expert advice to the committee.
* Dr Neil Rabin declared an indirect financial interest as he has received funding from Janssen-Cilag, Celgene (BMS), Takeda, Sanofi, Karyopharm, and Amgen for various reasons which include attending conferences and speaking at educational meetings and advisory boards. It was agreed that his declaration would not prevent Dr Neil Rabin from providing expert advice to the committee.
* No further interests were declared for this appraisal.
  + 1. The Chair led a discussion of the evidence presented to the committee. This information was presented to the committee by Dr Toby Smith (Clinical), Gabriel Rogers (Cost), and Nigel Westwood (Lay).
  1. Part 2a – Closed session (company representatives, patient and clinical experts and members of the public were asked to leave the meeting).
     1. The committee discussed confidential information submitted for this item.
  2. Part 2b – Closed session (external assessment group representatives were asked to leave the meeting)
     1. The committee then agreed on the content of the Draft Guidance (DG). The committee decision was reached by consensus.
     2. The committee asked the NICE technical team to prepare the Draft Guidance (DG) in line with their decisions.
* Further updates will be available on the topic webpage in due course: <https://www.nice.org.uk/guidance/awaiting-development/gid-ta10914>

1. **Appraisal of Lu vipivotide tetraxetan for treating PSMA-positive hormone-relapsed metastatic prostate cancer after 2 or more therapies [ID3840]**
   1. Part 1 – Open session
      1. The vice chair welcomed the invited experts, external assessment group representatives, members of the public and company representatives from Novartis.
      2. The vice 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.

* Dr Veline L’Esperance declared an indirect financial interest as her employer, Operose Health, received a grant from Novartis to undertake a Quality Improvement Project on lipid optimisation within primary care. Dr Veline L’Esperance stated that the grant was not related to this topic's disease area nor did she personally benefit financially from this grant. It was agreed that her declaration would not prevent Dr Veline L’Esperance from participating in discussions on this appraisal.
* Professor David McAllister declared a non-financial professional and personal interest, as part of the research he conducts uses data provided by sponsors (or competitors) provided via public trial repositories. Access is managed via an independent steering committee and neither he nor his organisation receive any funds from the trial companies for the work done. It was agreed that these declarations would not prevent Professor David McAllister from participating in the meeting.
* Dr Stephen Allen declared an indirect financial interest as Tackle Prostate Cancer receive funding from a large number of pharmaceutical companies. It was agreed that his declaration would not prevent Dr Stephen Allen from providing expert advice to the committee.
* Dr Amarnath Challapalli declared an indirect financial interest as he has received speaker fees and honoraria from Janssen, Sanofi, Bayer and Astellas. Dr Amarnath Challapalli was also part of ERG review panel for Lu-PSMA and was responsible for starting the EMES programme for Lu-PSMA at the University Hospitals Bristol NHS Foundation Trust. It was agreed that these declarations would not prevent Dr Amarnath Challapalli from providing expert advice to the committee.
* Professor Sabina Dizdarevic declared an indirect financial interests due to having been a member of an advisory board for Novartis, alongside receiving educational platform consultancy agreement for PSMA treatment, and receiving speaker fees from GE and Bayer. Professor Sabina Dizdarevic also declared an indirect interest, having been a BNSM Council member and Research Lead Chair of the ICSCNM, RCR/RC. It was agreed that these declarations would not prevent Professor Sabina Dizdarevic from providing expert advice to the committee.
* Professor Amit Bahl declared various indirect financial interests, having sat on advisory boards for Advisory boards for Sanofi, Astellas, BMS, Janssen, Pfizer, Bayer, EUSA, AAA (Novartis). Professor Amit Bahl has also sat on advisory boards for Accord, alongside having received sponsorship for meetings and educational lectures. It was agreed that these declarations would not prevent Professor Amit Bahl from providing expert advice to the committee.
* No further interests were declared for this appraisal.
  + 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 Draft Guidance (DG) or Final Draft Guidance (FDG). The committee decision was reached by consensus.
     2. The committee asked the NICE technical team to prepare the Final Draft Guidance (FDG) 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-ta10730>.

1. **Appraisal of Finerenone for treating chronic kidney disease in people with type 2 diabetes [ID3773]**
   1. Part 1 – Open session
      1. The chair welcomed the invited experts, external assessment group representatives, members of the public and company representatives from Bayer.
      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.

* Dr Warren Linley declared a direct financial interest as AstraZeneca is listed as a potential comparator company for the appraisal of Finerenone. He holds shares in AstraZeneca (in a self-invested pension) and has an agreement to potentially provide AstraZeneca with consulting services (although has not undertaken any consulting work in support of AstraZeneca or any of its products to date). It was agreed that his declaration would not prevent Dr Warren Linley from participating in discussions on this appraisal as an observer but would not participate in the decision-making process.
* Dr James Fotheringham declared an indirect financial interest as Boehringer Ingelheim have paid his employer for his time to undertake targeted literature reviews on health-related quality of life and predictors of progression in kidney disease. This is not for empagliflozin but rather a future technology which is currently just a string of letters and numbers for which they are designing a clinical trial. Dr James Fotheringham also declared a direct financial interest as he has signed a contract with Bayer to hold a meeting regarding NICE Processes in March. He has not been renumerated for this but will be once this has been carried out. It was agreed that these declarations would not prevent Dr James Fotheringham from participating in discussions on this appraisal.
* Prior to the meeting, Kieran McCafferty declared a direct financial interest as he has received speaker honoraria, and provided consultancy for Bayer, AstraZeneca, Vifor Fresenius, Napp, Pharmacosmos, Oncacre. Dr Kieran McCafferty also declared a direct non-financial interest because he is National Chief investigator for the FIGARO, FIDELIO and DEFINDER studies, and a grant holder for AstraZeneca and Chiesi. Dr Kieran McCafferty also declared an indirect non-financial interest because he is a member of the UK Kidney association, the European Renal Association, and the American society of Nephrology. It was agreed these declarations would not prevent Dr Kieran McCafferty from providing expert advice in this discussion.
* Prior to the meeting, Professor Stephen Bain declared a direct financial interest because in the past three years, he has had one contact with Bayer (an advisory board). He has also had contacts with the three of the companies that produce SGLT2 inhibitors (Astra Zeneca, Boehringer Ingelheim & Napp) but these are not competing with Finerenone in this clinical space. It was agreed that these declarations would not prevent Professor Stephen Bain from providing expert advice in this discussion.
* No further interests were declared for this appraisal.
  + 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 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 Final Draft Guidance (FDG). The committee decision was reached by consensus.
     2. The committee asked the NICE technical team to prepare the Final Draft Guidance (FDG) 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-ta10820>.

### Date of the next meeting

The next meeting of the Technology Appraisal Committee B will be held on Wednesday 8 February 2023 and will start promptly at 09:30.