

## Technology Appraisal Committee Meeting (Committee B)

**Minutes:** **Confirmed**

**Date and Time:** Wednesday 7 September, 10am to 5pm

**Venue:** Prospero House  
241 Borough High Street  
London  
SE1 1GA

<b>Present:</b>	1. Dr Amanda Adler 2. Dr Sanjeev Patel 3. Dr Ray Armstrong 4. Dr Jeff Aronson 5. Professor John Cairns 6. Mr Mark Chapman 7. Dr Mark Glover 8. Dr Sumeet Gupta 9. Mrs Anne Joshua 10. Dr Sanjay Kinra  11. Mr Chris O'Regan  12. Professor Stephen Palmer 13. Dr Danielle Preedy 14. Mr Alun Roebuck  15. Dr Marta Soares 16. Professor Ken Stein 17. Dr Nicky Welton	Present for all notes Present for all notes Present for all notes Present for all notes Present for notes 1 to 44 Present for all notes Present for all notes Present for all notes Present for notes 19 to 54 Present for all notes Present for notes 1 to 18, & 32 to 44 Present for notes 1 to 44 as a Committee member and for notes 45 to 53 as an ERG representative Present for all notes Present for all notes Present for notes 1 to 18 and notes 32 to 56 Present for all notes Present for all notes
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### In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Dr Melinda Goodall	Associate Director, National Institute for Health and Care Excellence	Present for notes 15 to 56
Jeremy Powell	Project Manager, National Institute for Health and Care Excellence	Present for all notes

Glenys Russell	Administrator, National Institute for Health and Care Excellence	Present for all notes
Anna Brett	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 19 to 31
Jasdeep Hayre	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 32 to 44
Rosie Lovett	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 44
Tom Palmer	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 32 to 44
Professor Aileen Clarke	Director of Warwick Evidence	Present for notes 1 to 16
Ewen Cummins Dr G.J. Melendez-Torres	Warwick Evidence Assistant Professor of HTA, Epidemiology and Evidence, Warwick Evidence	Present for notes 1 to 16 Present for notes 1 to 17
Professor Alasdair Coles	Prof of Neuroimmunology / Consultant Neurologist Trust, clinical expert nominated by Association of British Neurologists	Present for notes 1 to 16
Dr Gordon Mazibrada	Consultant Neurologist and Honorary Senior Lecturer clinical expert nominated by Novartis	Present for notes 1 to 14
Ms Amy Mackelden	Pharmaceuticals UK Ltd Patient expert Nominated by the Multiple Sclerosis Trust	Present for notes 1 to 14
Mrs Gillian Mitchell	Patient expert nominated by the MS Society	Present for notes 1 to 17
Malcolm Qualie	Pharmacy Lead, Specialised Services, NHS England NHS Commissioning Expert nominated by NHS England	Present for notes 1 to 14
Dr Charlotta Karner	HTA Analysis Manager, BMJ Technology Assessment Group	Present for notes 19 to 29

Andrea Berardi	HE Manager, BMJ Technology Assessment Group	Present for notes 19 to 29
Peter Cain	BMJ Technology Assessment Group	Present for notes 19 to 29
Professor Martin Hoyle	Director, PenTAG	Present for notes 32 to 42

### **Non-public observers:**

Edgar Masanga	Business Analyst - Resource Impact Assessment, NICE	Present for notes all notes
Liz Grainger	Medical Editor, NICE	Present for notes all notes
Jeremy Rodrigues	NICE Fellow	Present for notes all notes
Heidi Livingstone	NICE PIP	Present for notes all notes

### **Notes**

#### **Welcome**

1. The Chair welcomed all members of the Committee and other attendees present to the meeting. The Chair reviewed the agenda and timescales for the meeting, which included the appraisals of daclizumab for treating relapsing-remitting multiple sclerosis [ID827], nivolumab for treated or metastatic renal cell carcinoma [ID853], cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794] and apremilast moderate to severe - psoriasis (rapid review of TA368) [ID987].
2. The Chair informed the Committee of the non-public observers at this meeting: Linda Grainger, Edgar Masanga, Heidi Livingstone and Jeremy Rodrigues.
3. Apologies were received from Dr Neil Iosson, Dr Miriam McCarthy, Professor Ruairidh Milne, Professor John Poundsford, Dr Nigel De-Kare Silver and Nigel Westwood.

#### **Any other Business**

4. The Committee were given an update on other appraisals.

#### **Notes from the last meeting**

5. The minutes of the meeting held on 4 August were approved.

#### **Appraisal of daclizumab for treating relapsing-remitting multiple sclerosis [ID827]**

#### **Part 1 – Open session**

6. The Chair welcomed the invited experts: Professor Aileen Clarke, Professor Alasdair Coles, Ewen Cummins, Ms Amy Mackelden, Dr Gordon Mazibrada, Dr G.J. Melendez-Torres, Mrs Gillian Mitchell and Malcolm Qualie to the meeting and they introduced themselves to the Committee.
7. The Chair welcomed company representatives from Biogen to the meeting.

8. The Chair asked all Committee members to declare any relevant interests
  - 8.1. Dr Amanda Adler, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Dr Sumeet Gupta, Dr Sanjay Kinra, Mr Chris O'Regan, Professor Stephen Palmer, Dr Sanjeev Patel, Dr Danielle Preedy, Mr Alun Roebuck, Dr Marta Soares, Professor Ken Stein and Dr Nicky Welton all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of daclizumab for treating relapsing-remitting multiple sclerosis [ID827].
9. The Chair asked all NICE Staff to declare any relevant interests.
  - 9.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of daclizumab for treating relapsing-remitting multiple sclerosis [ID827].
10. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
  - 10.1. Professor Aileen Clarke, Ewen Cummins, Ms Amy Mackelden, Dr G.J. Melendez-Torres, Mrs Gillian Mitchell and Malcolm Qualie declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of daclizumab for treating relapsing-remitting multiple sclerosis [ID827].
  - 10.2. Professor Alasdair Coles declared a personal financial interest as he has received honoraria and research funding from SanofiGenzyme.
    - 10.2.1. It was agreed that this declaration would not prevent Professor Coles from participating in this section of the meeting
  - 10.3. Dr Gordon Mazibrada declared a non-personal financial interest as he has received financial support from all the companies manufacturing multiple sclerosis drugs in terms of service development at his hospital. He also declared a personal financial interest as he has participated in advisory board meetings at those companies.
    - 10.3.1. It was agreed that this declaration would not prevent Professor Coles from participating in this section of the meeting
11. The Chair introduced the lead team, Dr Mark Glover, Dr Dani Preedy and Dr Marta Soares who gave presentations on the clinical effectiveness and cost effectiveness of daclizumab for treating relapsing-remitting multiple sclerosis [ID827].
12. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

13. The Chair explained that "representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest" (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)" and all public attendees left the meeting.
14. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

15. Discussion on confidential information continued. This information was supplied by the company.
16. The Evidence Review Group representatives left the meeting.
17. The Committee continued to discuss the clinical and cost effectiveness of daclizumab for treating relapsing-remitting multiple sclerosis [ID827].
  - 17.1. The committee decision was based on consensus.
18. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

## **Appraisal of nivolumab for treated or metastatic renal cell carcinoma [ID853]**

### **Part 1 – Open session**

19. The Chair welcomed the Evidence Review Group representatives, Andrea Berardi, Peter Cain and Dr Charlotta Karner to the meeting.
20. The Chair welcomed company representatives from Bristol-Myers Squibb to the meeting.
21. The Chair asked all Committee members to declare any relevant interests
  - 21.1. Dr Amanda Adler, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Dr Sumeet Gupta, Mrs Anne Joshua, Dr Sanjay Kinra, Professor Stephen Palmer, Dr Sanjeev Patel, Dr Danielle Preedy, Mr Alun Roebuck, Professor Ken Stein and Dr Nicky Welton all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of nivolumab for treated or metastatic renal cell carcinoma [ID853].
  - 21.2. Mr Chris O'Regan declared a personal specific financial interest before the meeting as his employer (Merck Sharpe and Dohme) manufacture infliximab.
    - 20.2.1 It was agreed that this declaration would prevent Chris O'Regan from participating in this section of the meeting.

21.3. Dr Marta Soares declared a personal specific financial interest before the meeting as she has received fees from the company for advice on this product.

20.3.1 It was agreed that this declaration would prevent Marta Soares from participating in this section of the meeting.

22. The Chair asked all NICE Staff to declare any relevant interests.

22.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of nivolumab for treated or metastatic renal cell carcinoma [ID853].

23. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

23.1. Andrea Berardi, Peter Cain and Dr Charlotta Karner , all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of nivolumab for treated or metastatic renal cell carcinoma [ID853].

24. 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.

25. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

26. The Chair explained that "representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest" (Section 1(2) Public Bodies (Admission to Meetings) Act 1960" and all public attendees left the meeting.

27. The Chair then thanked the company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

28. Discussion on confidential information continued. This information was supplied by the company.

29. The Evidence Review Group representatives left the meeting.

30. The Committee continued to discuss the clinical and cost effectiveness of nivolumab for treated or metastatic renal cell carcinoma [ID853].

30.1. The committee decision was based on consensus.

31. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

**Cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794]**

**Part 1 – Open session**

32. The Chair welcomed the Assessment Group representative Professor Martin Hoyle to the meeting.
33. The Chair welcomed company representatives from Amgen and Merck Serono to the meeting.
34. The Chair asked all Committee members to declare any relevant interests
  - 34.1. Dr Amanda Adler, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Dr Sumeet Gupta, Dr Sanjay Kinra, Mr Chris O'Regan, Dr Sanjeev Patel, Dr Danielle Preedy, Mr Alun Roebuck, Dr Marta Soares, Professor Ken Stein and Dr Nicky Welton all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794].
  - 34.2. Professor Stephen Palmer declared a personal specific financial interest before the meeting as he has received fees from the company for advice on this product.
    - 34.2.1. It was agreed that this declaration would prevent Professor Palmer from participating in this section of the meeting.
35. The Chair asked all NICE Staff to declare any relevant interests.
  - 35.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794].
36. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
  - 36.1. Professor Martin Hoyle declared that he knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794].
37. The Chair introduced the key themes arising from the additional evidence submitted by the companies and the Assessment Group critique.

38. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
39. The Chair explained that "representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest" (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)" and all public attendees left the meeting.
40. The Chair then thanked the company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

41. Discussion on confidential information continued. This information was supplied by the company.
42. The Assessment Group representative left the meeting.
43. The Committee continued to discuss the clinical and cost effectiveness of cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794].
  - 43.1. The committee decision was based on consensus.
44. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

## **Apremilast moderate to severe - psoriasis (rapid review of TA368) [ID987]**

### **Part 1 – Open session**

45. Professor Stephen Palmer was present as an Evidence Review Group representative.
46. The Chair welcomed company representatives from Celgene to the meeting.
47. The Chair asked all Committee members to declare any relevant interests
  - 47.1. Dr Amanda Adler, Dr Ray Armstrong, Dr Jeff Aronson, Mr Mark Chapman, Dr Mark Glover, Dr Sumeet Gupta, Dr Sanjay Kinra, Dr Sanjeev Patel, Dr Danielle Preedy, Mr Alun Roebuck, Dr Marta Soares, Professor Ken Stein and Dr Nicky Welton all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794].
  - 47.2. Mr Chris O'Regan declared a personal specific financial interest before the meeting as his employer (Merck Sharpe and Dohme) manufacture infliximab.
    - 20.2.1 It was agreed that this declaration would prevent Chris O'Regan from participating in this section of the meeting.

48. The Chair asked all NICE Staff to declare any relevant interests.
  - 48.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of apremilast moderate to severe - psoriasis (rapid review of TA368) [ID987]
49. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
  - 49.1. Professor Stephen Palmer declared that he knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of apremilast moderate to severe - psoriasis (rapid review of TA368) [ID987].
50. 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.
51. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
52. The Chair explained that "representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest" (Section 1(2) Public Bodies (Admission to Meetings) Act 1960" and all public attendees left the meeting.
53. The Chair then thanked the Evidence Review Group and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

54. Discussion on confidential information continued. This information was supplied by the company.
55. The Committee continued to discuss the clinical and cost effectiveness of apremilast moderate to severe - psoriasis (rapid review of TA368) [ID987]
  - 55.1. The committee decision was based on consensus.
56. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

## **Date, time and venue of the next meeting**

57. Wednesday 5 October 2016 at Prospero House, 241 Borough High Street, London SE1 1GA.