

## Technology Appraisal Committee Meeting Committee C

**Minutes:** Confirmed

**Date and Time:** Tuesday 21 April 2015, 10:00 to 16.00

**Venue:** National Institute for Health and Care Excellence  
Level 1A, City Tower  
Piccadilly Plaza  
Manchester  
M1 4BT

|                 |  |  |
|-----------------|--|--|
| <b>Present:</b> | 1. Chair Professor Andrew Stevens<br>2. Professor Kathryn Abel<br>3. Dr David Black<br>4. David Chandler<br>5. Gail Coster<br>6. Professor Peter Crome<br>7. Professor Rachel Elliott<br>8. Dr Nigel Langford<br>9. Dr Suzanne Martin<br>10. Dr Patrick McKiernan<br>11. Dr Paul Miller<br>12. Professor Eugene Milne<br>13. Dr John Radford<br>14. Dr Peter Selby<br>15. Prof Matt Stevenson<br>16. Dr Paul Tappenden<br>17. Dr Robert Walton<br>18. Dr Judith Wardle | Present for all notes<br>Present for all notes<br>Present for notes 02 to 09<br>Present for all notes<br>Present for all notes |
|-----------------|--|--|

### In attendance:

|                      |  |                       |
|----------------------|--|-----------------------|
| Meindert Boysen      | Programme Director,<br>National Institute for<br>Health and Care<br>Excellence | Present for all notes |
| Dr Frances Sutcliffe | Associate Director,<br>National Institute for<br>Health and Care<br>Excellence | Present for all notes |
| Lori Farrar          | Project Manager,<br>National Institute for<br>Health and Care<br>Excellence    | Present for all notes |
| Joanne Ekeledo       | Administrator, National<br>Institute for Health and                            | Present for all notes |

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|-----------------------------------|---|----------------------------|
|                                   | Care Excellence   |                            |
| Pilar Pinilla-Dominguez           | Technical Analyst,<br>National Institute for<br>Health and Care<br>Excellence     | Present for notes 02 to 09 |
| Dr Sally Doss                     | Technical Adviser,<br>National Institute for<br>Health and Clinical<br>Excellence | Present for notes 02 to 09 |
| Caroline Hall                     | Technical Analyst,<br>National Institute for<br>Health and Care<br>Excellence     | Present for notes 10 to 14 |
| Fay McCracken                     | Technical Adviser,<br>National Institute for<br>Health and Clinical<br>Excellence | Present for notes 10 to 14 |
| Nigel Fleeman                     | ERG Representative,<br>LRIG   | Present for notes 02 to 08 |
| Adrian Bagust                     | ERG Representative,<br>LRIG   | Present for notes 02 to 08 |
| Laura Bojke                       | ERG Representative,<br>York   | Present for notes 10 to 13 |
| Mark Corbett                      | ERG Representative,<br>York   | Present for notes 10 to 13 |
| Eleftherios Sideris               | ERG Representative,<br>York   | Present for notes 10 to 13 |
| Dr Kostas G. Boboridis            | Clinical Expert   | Present for notes 02 to 08 |
| Professor Francisco<br>Figueiredo | Clinical Expert   | Present for notes 02 to 08 |
| David Chandler                    | Patient Expert  | Present for notes 10 to 13 |

|                     |                 |                            |
|---------------------|-----------------|----------------------------|
| Dr Philip Helliwell | Clinical Expert | Present for notes 10 to 13 |
| Helen McAteer       | Patient Expert  | Present for notes 10 to 13 |
| Dr Ruth Murphy      | Clinical Expert | Present for notes 10 to 13 |

**Non-public observers:**

|                 |   |                            |
|-----------------|---|----------------------------|
| Noreen Downes   | Healthcare Improvement Scotland   | Present for all notes      |
| Gabriel Rodgers | Technical Adviser<br>Health Economics<br>National Institute for<br>Health and Clinical<br>Excellence                            | Present for notes 10 to 14 |
| Stacy Wilkinson | Technical Analyst<br>Health and Social Care<br>Quality Programme<br>National Institute for<br>Health and Clinical<br>Excellence | Present for 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 Ciclosporin for treating dry eye disease, Apremilast for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.
2. The Chair informed the Committee of the non-public observers at this meeting: Noreen Downes, Gabriel Rodgers and Stacy Wilkinson
- 3.
4. Apologies were received from Professor Andrea Manca, Dr Anna O'Neill, Dr Claire McKenna, Dr Iain Miller, Prof Wasim Hanif and Professor Stephen O'Brien

## **Any other Business**

5. None

## **Appraisal of Ciclosporin for treating dry eye disease**

### **Part 1 – Open session**

6. The Chair welcomed the invited experts: Dr Kostas G. Boboridis and Professor Francisco Figueiredo to the meeting and they introduced themselves to the Committee.
7. The Chair welcomed company representatives from Santen GmbH to the meeting.
8. The Chair asked all Committee members to declare any relevant interests

Professor Kathryn Abel, Dr David Black, David Chandler, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Nigel Langford, Dr Suzanne Martin, Dr Patrick McKiernan, Dr Paul Miller, Professor Eugene Milne, Dr John Radford, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Dr Robert Walton, Dr Judith Wardle all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Ciclosporin for treating dry eye disease.

9. The Chair asked all NICE Staff to declare any relevant interests.
  - 9.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Ciclosporin for treating dry eye disease.
10. The Chair asked all other invited guests assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
  - 10.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Ciclosporin for treating dry eye disease.
  - 10.2. Dr Kostas G. Boboridis declared a personal non-specific pecuniary interest as he did some consultancy work for a comparator company named in this appraisal.
    - 10.2.1. It was agreed that this declaration would not prevent Dr Kostas G. Boboridis from participating in this section of the meeting

11. The Chair introduced the lead team, Dr Peter Selby, Professor Kathryn Abel and David Chandler who gave presentations on the clinical effectiveness and cost effectiveness of Ciclosporin for treating dry eye disease.
12. The Committee then discussed the clinical effectiveness, and cost effectiveness of Ciclosporin for treating dry eye disease on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
  - 12.1. The current clinical management of severe dry eye disease in the NHS, the place of ciclosporin within the treatment pathway, the appropriate comparator for ciclosporin and the use of other ciclosporin formulations which do not have a marketing authorisation in the UK and were not included in the NICE scope as comparators.
  - 12.2. The clinical effectiveness results from SANSIKA and SICCANOVE clinical trials, which compared ciclosporin with its vehicle.
  - 12.3. The clinical effectiveness results for the subgroup of people with Sjögren's syndrome and severe dry eye disease.
  - 12.4. The cost-effectiveness results, the assumptions and the relevance of the company's economic analysis comparing ciclosporin plus artificial tears with vehicle plus artificial tears.
  - 12.5. The importance of having a model reflecting clinical practice and thus, comparing the cost effectiveness of ciclosporin plus corticosteroids (if needed) and artificial tears, with that of corticosteroids (if needed) and artificial tears
  - 12.6. The potential for ciclosporin to be considered an innovative technology
13. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
14. 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.
15. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

16. Discussion on confidential information continued. This information was supplied by the company.
17. The Committee continued to discuss the clinical and cost effectiveness of Ciclosporin for treating dry eye disease.
18. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

## **Appraisal of Apremilast for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs**

### **Part 1 – Open session**

19. The Chair welcomed the invited experts: David Chandler, Dr Philip Helliwell, Helen McAteer and Dr Ruth Murphy to the meeting and they introduced themselves to the Committee.
20. The Chair welcomed company representatives from Celgene UK Ltd to the meeting.
21. The Chair asked all Committee members to declare any relevant interests
  - 21.1. Professor Kathryn Abel, Dr David Black, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Nigel Langford, Dr Suzanne Martin, Dr Patrick McKiernan, Dr Paul Miller, Professor Eugene Milne, Dr John Radford, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Dr Robert Walton, Dr Judith Wardle all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Appraisal of Apremilast for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.
  - 21.2. David Chandler, acting as patient expert for the Appraisal of Apremilast for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.
22. The Chair asked all NICE Staff to declare any relevant interests.
  - 22.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Appraisal of Apremilast for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.
23. The Chair asked all other invited guests assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
  - 23.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 Appraisal of Apremilast for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.

23.2. David Chandler declared a personal non specific pecuniary interest as he is lay member Technology Appraisal Committee C  
23.2.1. It was agreed that this declaration would not prevent David Chandler from participating in this section of the meeting

23.3. Helen McAteer declared a personal non specific pecuniary interest she explained the charity had received funding from Pharmaceutical industry including AbbVie and Novartis.  
23.3.1. It was agreed that this declaration would not prevent Helen McAteer from participating in this section of the meeting

23.4. Dr Ruth Murphy declared a personal non specific pecuniary interest she has acted in an advisory capacity to Celgene and other manufacturers  
23.4.1. It was agreed that this declaration would not prevent Dr Ruth Murphy from participating in this section of the meeting

23.5. Dr Philip Helliwell declared a personal non specific pecuniary interest as he received speaker fees from Celgene and other manufacturers. Also received research grants from manufacturers not including Celgene.  
23.5.1. It was agreed that this declaration would not prevent Dr Philip Helliwell from participating in this section of the meeting

24. The Chair introduced the lead team, Professor Matt Stevenson, Dr Nigel Langford and Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of Apremilast for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs

25. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Apremilast for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs on the basis of the evidence before them. They sought clarification and advice from the experts present. The discussions included:

- 25.1. The current clinical management of psoriatic arthritis in the NHS, the impact of the disease on patients and the goal of treatment
- 25.2. The possible positioning of apremilast within the pathway, the use of treatment sequences in the company's submission and the most appropriate comparators.
- 25.3. The clinical effectiveness results from the PSA-002, -003 and -004 studies, the results of the network meta-analysis and the generalisability of these results to the UK population.
- 25.4. The clinical effectiveness results for the TNF-alpha inhibitor naïve subgroup.
- 25.5. The cost-effectiveness results, the assumptions and the relevance of the company's economic analysis comparing treatment sequences with and without apremilast.
- 25.6. The positions and comparisons explored by the ERG
- 25.7. The most plausible ICER for apremilast
- 25.8. The potential for apremilast to be considered an innovative technology

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

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

## **Part 2 – Closed session**

29. Discussion on confidential information continued. This information was supplied by the company.
30. The Committee continued to discuss the clinical and cost effectiveness of Apremilast for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.
31. The Committee instructed the technical team to prepare the [Appraisal Consultation Document (ACD)] in line with their decisions.

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

32. Thursday, 21 May 2015, 10.00 to 17.00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.