# Technology Appraisal Committee Meeting Committee C

**Minutes:** Confirmed

**Date and Time:** Wednesday 22 July 2015, 10:00 – 17:00

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

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| **Present:** | 1. Chair Professor Andrew Stevens | Present for all notes |
| | 2. Professor Kathryn Abel | Present for all notes |
| | 3. Dr David Black | Present for all notes |
| | 4. David Chandler | Present for notes 01 to 09<br>Present for notes 15 to 19 |
| | 5. Gail Coster | Present for all notes |
| | 6. Professor Peter Crome | Present for all notes |
| | 7. Professor Rachel Elliott | Present for all notes |
| | 8. Dr Iain Miller | Present for all notes |
| | 9. Professor Eugene Milne | Present for all notes |
| | 10. Professor Andrea Manca | Present for all notes |
| | 11. Stephen O'Brien | Present for all notes |
| | 12. Dr Claire Rothery | Present for all notes |
| | 13. Dr Peter Selby | Present for all notes |
| | 14. Prof Matt Stevenson | Present for notes 01 to 14 |
| | 15. Dr Paul Tappenden | Present for all notes |
| | 16. Dr Robert Walton | Present for all notes |
| | 17. Dr Judith Wardle | Present for all notes |

**In attendance:**

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

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| | Care Excellence | |
| Boglarka Mikudina | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 15 to 19 |
| Zoe Garrett | Technical Adviser, National Institute for Health and Clinical Excellence | Present for notes 15 to 19 |
| Victoria Kelly | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 05 to 09 |
| Jo Holden | Technical Adviser, National Institute for Health and Clinical Excellence | Present for notes 05 to 09 |
| Carl Prescott | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 10 to 14 |
| Nicola Hay | Technical Adviser, National Institute for Health and Clinical Excellence | Present for notes 10 to 14 |
| Fiona Pearce | Technical Adviser, National Institute for Health and Clinical Excellence | Present for notes 10 to 14 |
| **Non-public observers:** | | |
| Jane Lynn | NICE Observer | Present for notes 01 to 14 |
| Sally Doss | NICE Observer | Present for notes 01 to 09 |
| Liz Woodeson | Department of Health | Present for notes 01 to 19 |

## 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 Idelalisib for previously treated chronic lymphocytic leukaemia , Apremilast for treating active psoriatic arthritis, Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after

conventional DMARDs only have failed

2. The Chair informed the Committee of the non-public observers at this meeting: Jane Lynn, Liz Woodeson, Sally Doss

3. Apologies were received from Dr Anna O'Neill, Dr Nigel Langford, Dr Patrick McKiernan , Dr Paul Miller, and Dr Suzanne Martin

**Any other Business**

4. None

**Appraisal of Idelalisib for previously treated chronic lymphocytic leukaemia**

**Part 1 – Open session**

5. The Chair welcomed the invited experts: Professor Christopher Fegan and Dr Francesco Forconi to the meeting and they introduced themselves to the Committee.

6. The Chair welcomed company representatives from Gilead Science Ltd to the meeting.

7. The Chair asked all Committee members to declare any relevant interests

   7.1. Professor Kathryn Abel, Dr David Black, David Chandler, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Iain Miller, Professor Eugene Milne, Professor Andrea Manca, Stephen O'Brien, Dr Claire Rothery, Dr Peter Selby, Prof Matt Stevenson, Dr Judith Wardle, Dr Robert Walton, Dr Paul Tappenden 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 Idelalisib for previously treated chronic lymphocytic leukaemia.

   7.2. Professor Stephen O'Brien declared a non-personal specific pecuniary interest as he is a member of the NCRI Clinical Studies Group (CSG), which oversees a portfolio of leukaemia trials in the UK. He has no current involvement with CLL trials – his involvement is in CML. Trials of idelalisib have been conducted in our department in Newcastle he has received no funding. Over the last 12 months his University and/or NHS Trust has received research funding for clinical trial work from the following companies: Pfizer.

   9.2.1 It was agreed that this declaration would not prevent Professor Stephen O'Brien from participating in this section of the meeting.

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

   8.1. 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 Idelalisib for previously treated chronic lymphocytic leukaemia.

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9. The Chair asked all other invited guests assessment group/ERG and invited experts, not including observers) to declare their 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 Idelalisib for previously treated chronic lymphocytic leukaemia.

    9.2. Dr Francesco Forconi declared a personal non pecuniary interest. He attended consultancy for Gilead on 8 May 2015 at Gilead's offices in London were he acted as clinical expert in a mock AC Meeting for Idelalisib.
        9.2.1. It was agreed that this declaration would not prevent Dr Francesco Forconi from participating in this section of the meeting

    9.3. Professor Christopher Fegan declared a personal non pecuniary interest. He received honorary speaker fees from Gilead Sciences.
        9.3.1. It was agreed that this declaration would not prevent Professor Christopher Fegan from participating in this section of the meeting.

10. 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.

11. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Idelalisib for previously treated chronic lymphocytic leukaemia 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:

    11.1. Refractory and high risk population definitions in CLL
    11.2. Use of idelalisib in untreated 17p and TP53 populations
    11.3. Intravenous immunoglobulin dosing
    11.4. EQ-5D data
    11.5. Most plausible ICERs
    11.6. End of Life criteria.

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, company representatives and academic group 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 Committee continued to discuss the clinical and cost effectiveness of Idelalisib for previously treated chronic lymphocytic leukaemia

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

**Appraisal of Apremilast for treating active psoriatic arthritis**

**Part 1 – Open session**

18. The Chair welcomed company representatives from Celgene to the meeting.

19. The Chair asked all Committee members to declare any relevant interests

    19.1. Professor Kathryn Abel, Dr David Black, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Iain Miller, Professor Eugene Milne, Professor Andrea Manca, Stephen O'Brien, Dr Claire Rothery, Dr Peter Selby, Prof Matt Stevenson, Dr Judith Wardle, Dr Robert Walton, Dr Paul Tappenden 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 Apremilast for treating active psoriatic arthritis .

    19.2. David Chandler, he acted as a patient expert for this topic at the previous meeting in May.

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

    20.1. 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 Apremilast for treating active psoriatic arthritis

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

    21.1. 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 Apremilast for treating active psoriatic arthritis.

22. 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.

23. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Apremilast for treating active psoriatic arthritis on the basis of the evidence before them. The discussions included:

    23.1. The consultation comments received on the Appraisal Consultation Document
    23.2. The updated clinical evidence submitted by the company in response to the Appraisal Consultation Document, including information about disease progression (radiographic progression of disease and the HAQ-DI outcome).
    23.3. The updated cost-effectiveness evidence submitted by the company in response to the Appraisal Consultation Document, including updated cost-effectiveness results
    23.4. The critique of the company Appraisal Consultation Document response by the Evidence Review Group, including the Evidence Review Group scenario analyses

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

25. 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.

26. 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**

27. The Committee continued to discuss the clinical and cost effectiveness of Apremilast for treating active psoriatic arthritis.

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

**Appraisal of Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed**

**Part 1 – Open session**

29. The Chair welcomed the invited experts: Professor Ernest Choy , Dr Frank McKenna and Dr Ben Parker to the meeting and they introduced themselves to the Committee.

30. The Chair welcomed company representatives from AbbVie, BMS, Hospira, MSD, Napp, Pfizer, Roche, and UCB Celltech to the meeting.

31. The Chair asked all Committee members to declare any relevant interests

31.1. Professor Kathryn Abel, Dr David Black, David Chandler, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Iain Miller, Professor Eugene Milne, Professor Andrea Manca, Stephen O'Brien, Dr Claire Rothery, Dr Peter Selby, Dr Judith Wardle, Dr Robert Walton, Dr Paul Tappenden 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 Idelalisib for previously treated chronic lymphocytic leukaemia.

31.2. Professor Stephen O'Brien declared a non-personal financial specific interest as he has received support from BMS to attend scientific meetings. Over the past 12 months his university/NHS trust has received research funding for clinical trials from Novartis, Pfizer and BMS.

31.2.1. It was agreed that this declaration would not prevent Professor Stephen O'Brien from participating in this section of the meeting.

31.3. Professor Matt Stevenson, conflicted for this topic He is a member of the Assessment Group for this appraisal

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

32.1. 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 Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed

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

33.1. 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 Idelalisib for previously treated chronic lymphocytic leukaemia.

33.2. Dr Frank McKenna declared a personal non pecuniary interest he acted as a clinical investigator for three of the companies.

33.2.1. It was agreed that this declaration would not prevent Dr Frank McKenna from participating in this section of the meeting.

33.3. Dr Ben Parker declared a non- personal financial specific interest. He received speaker, adviser and honorary fees from AbbVie, Pfizer and BMS

33.3.1. It was agreed that this declaration would not prevent Dr Ben Parker from participating in this section of the meeting.

33.4. Professor Ernest Choy declared a personal non- pecuniary interest. He had taken part in clinical trials with all the companies

33.4.1. It was agreed that this declaration would not prevent Professor Ernest Choy from participating in this section of the meeting.

34. 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.

35. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed 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:

35.1. The impact of the disease on people with the condition and the management of rheumatoid arthritis.

35.2. The different measures of response used in clinical practice and in the clinical trials

35.3. The place of biological DMARDs in the treatment pathway.

35.4. The clinical effectiveness of biological DMARDs compared with conventional DMARDs, the evidence presented by the Assessment Group and the update of the network meta-analysis

35.5. The comments from ACD consultation regarding defining patients with rapid disease progression

35.6. The different assumptions of the economic models submitted by the companies and the model developed by the Assessment Group (i.e. underlying disease progression for people on biological DMARDs and for people on conventional DMARDs, the different methods to obtain EQ-5D from HAQ scores, the discount rates)

35.7. The cost-effectiveness evidence and the most appropriate ICERs for the different populations (i.e. population with severe active rheumatoid arthritis not previously treated with methotrexate, severe active rheumatoid arthritis previously treated with methotrexate, moderate active rheumatoid arthritis)

35.8. The results of the work of the Decision Support Unit on HAQ progression and its impact on the cost-effectiveness results

35.9. The Assessment Group's additional analyses using the rates of HAQ progression for people with rapid disease progression

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

37. 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.

38. 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**

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

40. The Committee continued to discuss the clinical and cost effectiveness of Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed

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

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

42. Tuesday 18 August 2015,10:00 – 17:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.