Technology Appraisal Committee Meeting Committee C

Minutes: Confirmed

Date and Time: **Thursday 21 May 2015**, **10:00 – 17:00**

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

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. Gail Coster	Present for all notes
	5. Professor Rachel Elliott	Present for all notes
	6. Dr Nigel Langford	Present for all notes
	7. Dr Iain Miller	Present for all notes
	8. Dr Paul Miller	Present for notes 10 to 14
	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 10 to 14
	15. Dr Robert Walton	Present for all notes
	16. Dr Judith Wardle	Present for all notes

In attendance:

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 Care Excellence	Present for all notes
Boglarka Mikudina	Technical Analyst, National Institute for	Present for notes 05 to 09

	Health and Care Excellence	
Zoe Garrett	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 05 to 09
Victoria Kelly	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 10 to 14
Dr Sally Doss	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 10 to 14
Professor Matt Stevenson	AG Representative	Present for notes 05 to 08
Laura Gibson	AG Representative	Present for notes 05 to 08
Monica Hernandez	AG Representative	Present for notes 05 to 08
Allan Wailoo	AG Representative	Present for notes 05 to 08
Professor Eileen Clarke	ERG Representative	Present for notes 10 to 13
Dr Joshua Pink	ERG Representative	Present for notes 10 to 13
Dr Alexander Tsertsvadze	ERG Representative	Present for notes 10 to 13
Professor Ernest Choy	Clinical Expert	Present for notes 05 to 08
Dr Frank McKenna	Clinical Expert	Present for notes 05 to 08
Dr Ben Parker	Clinical Expert	Present for notes 05 to 08
Alisa Bosworth	Patient Expert	Present for notes 05 to 08
Professor Christopher Fegan	Clinical Expert	Present for notes 10 to 13
Dr Francesco Forconi	Clinical Expert	Present for notes 10 to 13
Tricia Gardom	Patient Expert	Present for notes 10 to 13
Nick York	Patient Expert	Present for notes 10 to 13

Non-public observers:

Dr Chris Gibbons	NICE Observer	Present for notes 05 to 09
Paul Levay	NICE Observer	Present for notes 05 to 09

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 Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, abatacept and tocilizumab for the treatment of rheumatoid arthritis (review of TA guidance 130, 186, 224, 234 and part review of TA guidance 225 and 247) and Idelalisib for previously treated chronic lymphocytic leukaemia.

2. The Chair informed the Committee of the non-public observers at this meeting: Dr Chris Gibbons and Paul Levay.

3. Apologies were received from Dr Anna O'Neill, David Chandler, Dr Patrick McKiernan, Dr Paul Tappenden, Professor Peter Crome, Dr Suzanne Martin, and Dr John Radford.

Any other Business

4. None

Appraisal of Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, abatacept and tocilizumab for the treatment of rheumatoid arthritis (review of TA guidance 130, 186, 224, 234 and part review of TA guidance 225 and 247)

Part 1 – Open session

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

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

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

    7.1. Professor Kathryn Abel, Dr David Black, Gail Coster, Professor Rachel Elliott, Dr Iain Miller, Professor Eugene Milne, Professor Andrea Manca, Dr Nigel Langford, Stephen O'Brien, Dr Claire Rothery, Dr Peter Selby, Prof Matt Stevenson, Dr Judith Wardle, Dr Robert Walton 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, abatacept and tocilizumab for the treatment of rheumatoid arthritis (review of TA guidance 130, 186, 224, 234 and part review of TA guidance 225 and 247).

    7.2. 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.

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

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

7.3.1. Dr Paul Miller, conflicted. Employed by a comparator manufacturer within the last 12months

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

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

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

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

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

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

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

9.4.1. It was agreed that this declaration would not prevent Professor Ernest Choy 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 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:

11.1. The impact of the disease on people with the condition and the management of rheumatoid arthritis.
11.2. The different measures of response used in clinical practice and in the clinical trials
11.3. The place of biological DMARDs in the treatment pathway.
11.4. The clinical effectiveness of biological DMARDs compared with conventional DMARDs and the evidence presented by the Assessment Group
11.5. 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)
11.6. 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)
11.7. The results of the work of the Decision Support Unit on HAQ progression and its impact on the cost-effectiveness results

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.
15.

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

18. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of Idelalisib for previously treated chronic lymphocytic leukaemia

Part 1 – Open session

19. The Chair welcomed the invited experts: Professor Christopher Fegan, Dr Francesco Forconi, Tricia Gardom and Nick York, to the meeting and they introduced themselves to the Committee.

20. The Chair welcomed company representatives from Gilead Sciences 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 Rachel Elliott, Dr Iain Miller, Dr Paul Miller, Professor Eugene Milne, Professor Andrea Manca, Dr Nigel Langford, Stephen O'Brien, Dr Claire Rothery, Dr Peter Selby, Prof Matt Stevenson, Dr Judith Wardle, Dr Robert Walton 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.

    21.2. 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.

    21.2.1. It was agreed that this declaration would not prevent Professor Stephen O'Brien 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 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.

23. The Chair asked all other invited guests 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 Idelalisib for previously treated chronic lymphocytic leukaemia.

    23.2. 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.

23.2.1. It was agreed that this declaration would not prevent Dr Francesco Forconi from participating in this section of the meeting.

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

23.4. Nick York declared a non-personal specific pecuniary interest as a Trustee he had accepted education grants from the company and the comparators.
23.4.1. It was agreed that this declaration would not prevent Nick York from participating in this section of the meeting.

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 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:

25.1. The impact of the disease on people with the condition and the management of CLL.
25.2. The clinical effectiveness of idelalisib compared with the comparators listed in the NICE scope in people with previously treated CLL and the untreated sub group.
25.3. The cost-effectiveness evidence and the most appropriate ICERs for people with previously treated CLL and the untreated sub group.
25.4. End of life considerations.

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 Idelalisib for previously treated chronic lymphocytic leukaemia.

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. Wednesday , 22 July 2015, 10:00 – 17:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.