Technology Appraisal Committee Meeting (Committee [A])

Minutes: Confirmed

Date and Time: 27th January 2015

Venue: **The Royal College of General Practitioners, 30 Euston Square, London, NW1 2HD (EXTERNAL VENUE)**

Present:	1. Chair Jane Adam	Present for all notes
	2. Professor Iain Squire	Present for all notes
	3. Dr Ian Lewin	Present for all notes
	4. Mr Adrian Griffin	Present for notes 1 to 18
	5. Dr Brian Shine	Present for all notes
	6. Dr Paul Robinson	Present for notes for 1 to 32
	7. Dr Jeremy Braybrooke	Present for all notes
	8. Dr Gerardine Bryant	Present for all notes
	9. Dr Peter Sims	Present for all notes
	10. Dr Eldon Spackman	Present for all notes
	11. Mr David Thomson	Present for all notes
	12. Mrs Pamela Rees	Present for all notes
	13. Dr Graham Ash	Present for all notes
	14. Professor Olivia Wu	Present for all notes
	15. Dr Andrew England	Present for all notes
	16. Professor Aileen Clarke	Present for all notes
	17. Dr John Watkins	Present for all notes
	18. Ellen Rule	Present for all notes
	19. Mr Stephen Sharpe	Present for all notes

In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Janet Robertson	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Bijal Joshi	Project Manager, National Institute for Health and Care Excellence	Present for all notes

Marcia Miller	Technology Appraisal Administrator, National Institute for Health and Care Excellence	Present for all notes
Christian Griffiths	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 18
Zoe Charles	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 18
Mary Hughes	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 19 to 32
Sally Doss	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 19 to 32
Helen Tucker	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 33 to 46
Raisa Sidhu	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 33 –to 46

Clinical Experts

Professor Derek Manas	Consultant Hepatobiliary and Transplant Surgeon Nominated by Novartis	Present for notes 1 to 18
Dr Will Lester	Consultant Haematologist nominated by Royal College of Pathologists And the British Society of Haematology	Present for note 19 to 32
Dr Tim Nokes	Consultant Haemaologists	Present for notes 19 to 32

	Nominated by BMS & Pfizer	
Dr John Mansfield	Consultant Gastroenterologist And Senior Lecturer nominated by British Gastroenterologist	Present for notes 33-46

Patient Experts

Mr Richard Hall	Patient expert nominated by Liver4Life	Present for notes 1 to 18
Mr Andrew Langford	Patient expert nominated by British Liver Trust	Present for notes 1 to 18
Mrs Diane Eaton	Patient expert nominated by AntiCoagulation Europe	Present for notes 19 to 32
Mrs Beverly Hunt	Patient expert nominated by The Thrombosis Society: Lifeblood the Charity	Present for notes 19 to 32
Miss Elizabeth Cleaver	Patient expert nominated by Crohn's and Colitis UK	Present for notes 33 to 46
Mr Kameron Singh	Patient expert nominated by Crohn's and Colitis UK	Present for notes 33 to 46

Evidence Review Group PenTAG

Adeline Durand	Senior Health Economist	Present for notes 1 to 18
Dr Ruben Mujica Mota	Economist	Present for notes 1 to 18
Mitesh Nakum	Economist	Present for notes 1 to 18

Evidence Review Group - Liverpool Implementation Review Group

Professor Adrian Bagust		Present for notes 19 to 32
Dr Janette Greenhalgh	Economist	Present for notes 19 to 32
Miss Marty Richardson	Economist	Present for notes 19 to 32

Evidence Review Group School of Health Assessment and Related Research

Alice Bessey	Economist	Present for notes 33 to 42
Munira Essat	Economist	Present for notes 33 to 42
Paul Tappenden	Economist	Present for notes 33 to 42

Non-public observers:

Melinda Kay	NICE	Present for all notes
Heidi Livingstone	NICE	Present for all notes
Linda Grainger	NICE	Present for notes 1 to 18
Ria Skelton	NICE	Present for notes 1 to 32
Dr Andrew Titman	LRiG	Present for notes 19 to 32

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 Everolimus for preventing organ rejection in liver transplantation.

2. The Chair informed the Committee of the non-public observers at this meeting: Linda Grainger, Melinda Kay, Heidi Livingstone, and Ria Skelton

3. Apologies were received from Dr Thanos Athansiou, Dr Simon Bond, Professor John McMurray, Dr Anne McCune, Dr Mohit Misra and Mrs Sarah Parry.

Notes from the last meeting

4. The minutes from the last meeting was agreed

Appraisal of **Everolimus for preventing organ rejection in liver transplantation.**

Part 1 – Open session

5. The Chair welcomed the invited experts and Evidence Review Group: Richard Hall, Andrew Langford, Professor Derek Manas, Adeline Durand, Dr Ruben Mujica Mota and Mitesh Nakrum. to the meeting and they introduced themselves to the Committee.

6. The Chair welcomed company representatives from Novartis to the meeting.

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

7.1. Dr Jane Adam, Dr Ian Lewin, Mr Adrian Griffin, Dr Brian Shine, Dr Paul Robinson, Dr Jeremy Braybrooke, Dr Gerardine Bryant, Dr Peter Sims, Mr David Thomson, Mrs Pamela Rees, Dr Graham Ash, Professor Olivia Wu , Dr Andrew England, Professor Aileen Clarke, Dr John Watkins, Dr Eldon Spackman and Ellen Rule 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 Everolimus for preventing organ rejection in liver transplantation.

7.2. Professor Iain Squire declared a personal non- specific pecuniary interest as he is has accepted a honorarium for participation in education events and advisory boards from the company in relation to heart failure treatment. He has not involvement with the agent under discussion in the current appraisal.

7.3.2 It was agreed that this declaration would not prevent Professor Iain Squire 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 Everolimus for preventing organ rejection in liver transplantation.

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9. The Chair asked all other invited guests: 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 Everolimus for preventing organ rejection in liver transplantation.

10. The Chair introduced the lead team, Dr Ian Lewin with Mr David Thomson and Mr Adrian Griffin who gave presentations on the clinical effectiveness and cost effectiveness of **Everolimus for preventing organ rejection in liver transplantation.**

11. **The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of** Everolimus for preventing organ rejection in liver transplantation.

12. 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 nature of the condition, perspective of people before and after having a liver transplant
    12.2. Current treatment for preventing organ rejection in liver transplantation
    12.3. Whether the H2304 study was generalisable to UK clinical practice and the results from this study
    12.4. The appropriateness of the company's approach to using a patient level simulation for their economic model
    12.5. The plausibility of the health states and utility values used in the company's economic model
    12.6. Interpretation and appropriateness of the comparator data to the UK setting with respect to target whole blood trough levels of tacrolimus.
    12.7. The uncertainty in the cost-effectiveness estimates for everolimus as a result of instability of the economic model, long time horizon, and the potential discrepancy of how total costs were included in the model for the comparator technologies.
    12.8. The Committee's view on the most plausible ICERs

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. The Committee continued to discuss the clinical and cost effectiveness of Everolimus for preventing organ rejection in liver transplantation.

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

Appraisal of Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism

Part 1 – Open session

18. The Chair welcomed the invited experts and Evidence Review Group: Mrs Diane Eaton, Dr Will Lester, Dr Tim Nokes, Professor Adrian Bagust, Dr Janette Greenhalgh and Miss Marty Richardson to the meeting and they introduced themselves to the Committee.

19. The Chair welcomed company representatives from BMS & Pfizer to the meeting.

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

Dr Jane Adam, Professor Iain Squire, Dr Ian Lewin, Dr Brian Shine, Dr Paul Robinson, Dr Jeremy Braybrooke, Dr Gerardine Bryant, Dr Peter Sims, Mr David Thomson, Mrs Pamela Rees, Dr Graham Ash, Professor Olivia Wu , Dr Andrew England, Professor Aileen Clarke, Dr John Watkins, Dr Eldon Spackman and Ellen Rule 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 Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism

20.1. **Dr Eldon Spackman declared personal specific pecuniary interest Eldon has reviewed a cost-effectiveness model of apixaban for atrial fibrillation in 2012 for BMS.**
7.2.1 It was agreed that this declaration would not prevent Dr Eldon Spackman from participating in this section of the meeting and he was absent from the meeting.

20.2. Mr Adrian Griffin declared personal specific pecuniary interest as he is employed by Johnson and Johnson who is a competitor company in some markets.

21.2.1 It was agreed that this declaration would prevent Mr Adrian Griffin from participating in this section of the meeting and he was absent from the meeting.

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

21.1. Dr Will Lester, Professor Adrian Bagust, Dr Janette Greenhalgh and Miss Marty Richardson 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 Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism.

21.2. Mrs Diane Eaton declared a non-personal specific pecuniary interest as AntiCoagulation Europe has received funding between 2013 – 2014. This was for the development of patient centred education and information tools (inforgraphic health for public). She has not received financial remittance.

22.2.1 It was agreed that this declaration would not prevent Mrs Diane Eaton from participating in this section of the meeting.

21.3. Dr Tim Nokes declared personal specific pecuniary interest as he has received fees for lecturing and attendance at a conference from Bayer and Boehringer Ingelheim. He has also received fees for attending advisory board for Bayer, Boehringer Ingelheim, Bristol Myers-Squibb, Pfizer and Daiichi Sankyo.

22.3.1 It was agreed that this declaration would not prevent Dr Tim Nokes from participating in this section of the meeting.

22. The Chair asked all other invited guests: ERG and invited experts, not including observers) to declare their 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** Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism

23. The Chair introduced the lead team, Dr Paul Robinson with Mrs Pamela Rees and Dr Brian Shine who gave presentations on the clinical effectiveness and cost effectiveness of Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism

24. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism 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:

24.1. The use of warfarin, rivaroxaban and dabigatran etexilate in clinical practice and the advantages and disadvantages of apixaban and the other anticoagulants used for treating deep vein thrombosis and pulmonary embolism.

24.2. The clinical trial data for apixaban from the AMPLIFY and AMPLIFY-EXT trials

24.3. The company's approach of indirectly comparing apixaban with rivaroxaban and dabigatran etexilate using network meta-analysis and the results of these analyses.

24.4. The source of the company's assumptions on utility values and consistency with previous appraisals

24.5. The base case and sensitivity analyses presented by the company and the ERG for a 6 month treatment or lifelong treatment with apixaban

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 experts, company representatives and academic group 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 Committee continued to discuss the clinical and cost effectiveness of Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism

30. The Committee instructed the technical team to prepare the Final Appraisal Document (FAD) or Appraisal Consultation document (ACD) in line with their decisions

Appraisal of Vedolizumab for treating moderately to severely active ulcerative colitis [ID691]

Part 1 – Open session

31. The Chair welcomed the invited experts and Evidence Review Group: Alice Bessey, Munira Essat Paul Tappenden and Dr John Mansfield to the meeting and they introduced themselves to the Committee.

32. The Chair welcomed company representatives from Takeda UK to the meeting.

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

    33.1. Dr Jane Adam, Professor Iain Squire, Dr Ian Lewin, Dr Brian Shine, Dr Paul Robinson, Dr Jeremy Braybrooke, Dr Gerardine Bryant, Dr Peter Sims, Mr David Thomson, Mrs Pamela Rees, Dr Graham Ash, Professor Olivia Wu, Dr Andrew England, Professor Aileen Clarke, Dr John Watkins, Dr Eldon Spackman and Ellen Rule 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 Vedolizumab for treating moderately to severely active ulcerative colitis.

    33.2. Mr Adrian Griffin declared a personal specific pecuniary interest as he is employed by Johnson & Johnson, a competitor company in some markets

    35.2.1 It was agreed that this declaration would prevent Mr Adrian Griffin from participating in this section of the meeting and he was absent from the meeting

    33.3. Dr Paul Robinson declared a personal specific pecuniary interest as he is employed by Merck, Sharpe and Dohme who markets infliximab and golimumab, both of which are used in severe ulcerative colitis.
    35.3.2 It was agreed that this declaration would prevent Dr Paul Robinson from participating in this section of the meeting and he was absent from the meeting

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

    34.1. 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 Vedolizumab for treating moderately to severely active ulcerative colitis.

35. The Chair asked all other invited guests: ERG and invited experts, not including observers) to declare their relevant interests.

35.1. Alice Bessey, Munira Essat and Paul Tappenden 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 Vedolizumab for treating moderately to severely active ulcerative colitis

35.2. Dr John Mansfield declared a personal specific pecuniary interest as he has chaired a regional meeting for Takeda.
37.2.1 It was agreed that this declaration would not prevent Dr John Mansfield from participating in this section of the meeting.

36. 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.

37. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Vedolizumab for treating moderately to severely active ulcerative colitis 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:

37.1. The comments from consultees, commentators and from the website on the Appraisal Consultation Document

37.2. The revised cost-effectiveness estimates (which also incorporated a revised patient access scheme) submitted by the company in people in whom treatment with a TNF-alpha inhibitor has failed

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 experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

41. The Committee continued to discuss the clinical and cost effectiveness **Vedolizumab for treating moderately to severely active ulcerative colitis.**

42. 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

43. Wednesday 25th February 2015 at the Royal College of General Practitioners, 30 Euston Square, London, NW1 2HD