Technology Appraisal Committee Meeting Committee C

Minutes: Confirmed

Date and Time: **Wednesday 18 February 2015, 10:00 – 14:30**

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

Present:	1. Chair Professor Eugene Milne	Present for all notes
	2. Professor Kathryn Abel	Present for all notes
	3. David Chandler	Present for all notes
	4. Gail Coster	Present for all notes
	5. Professor Peter Crome	Present for all notes
	6. Professor Rachel Elliott	Present for all notes
	7. Dr Nigel Langford	Present for all notes
	8. Dr Claire McKenna	Present for all notes
	9. Dr Iain Miller	Present for all notes
	10. Professor Stephen O'Brien	Present for all notes
	11. Dr Anna O'Neill	Present for all notes
	12. Dr John Radford	Present for all notes
	13. Dr Peter Selby	Present for all notes
	14. Prof Matt Stevenson	Present for all notes
	15. Dr Judith Wardle	Present for all notes

In attendance:

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
Richard Diaz	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 02 to 09
Nwamaka Umeweni	Technical Adviser,	Present for notes 02 to 09

	National Institute for Health and Clinical Excellence	
Christian Griffiths	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 10 to 15
Dr Sally Doss	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 10 to 15
Robert Wolff	ERG Representative, Kleinjen	Present for notes 02 to 08
Maiwenn Al	ERG Representative, Kleinjen	Present for notes 02 to 08
Dr Andrew Davies	Clinical Expert	Present for notes 02 to 08
Dr Paul Farquhar-Smith	Clinical Expert	Present for notes 02 to 08
Karen Irwin	Patient Expert	Present for notes 02 to 08

Non-public observers:

Leanne Wakefield	HST Programme Manager National Institute for Health and Clinical Excellence	Present for notes all notes
Stephanie Yates	Project Coordinator National Institute for Health and Clinical Excellence	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 Naloxegol for treating opioid induced constipation.

2. The Chair informed the Committee of the non-public observers at this meeting: Leanne Wakefield and Stephanie Yates

3.

4. Apologies were received from Dr Alan Haycox, Dr Allyson Lipp, Professor Andrea Manca, Professor Andrew Stevens, Dr David Black, Dr Patrick McKeirnan, Dr Paul Miller, Dr Robert Walton, Dr Suzanne Martin, and Professor Wasim Hanif.

Any other Business

5. None

Appraisal of Naloxegol for treating opioid induced constipation

Part 1 – Open session

6. The Chair welcomed the invited experts: Dr Andrew Davies, Dr Paul Farquhar-Smith and Karen Irwin to the meeting and they introduced themselves to the Committee.

7. The Chair welcomed company representatives from Astrazeneca UK Ltd to the meeting.

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

    8.1. Professor Kathryn Abel, Gail Coster, David Chandler,Professor Peter Crome, Professor Rachel Elliott, Dr Nigel Langford, Dr Claire McKenna, Dr Iain Miller, Professor Stephen O'Brien, Dr Anna O'Neill, Dr John Radford, Dr Peter Selby, Prof Matt Stevenson, 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 Naloxegol for treating opioid induced constipation.

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 Naloxegol for treating opioid induced constipation.

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 Naloxegol for treating opioid induced constipation.

    10.2. Dr Andrew Davies declared a personal non specific pecuniary interest as he has attended an Astrazeneca Advisory Board meeting and received honorary payments for lectures

        10.2.1. It was agreed that this declaration would not prevent Dr Andrew Davies from participating in this section of the meeting

11. The Chair introduced the lead team, Dr Judith Wardle, David Chandler and Dr Claire McKenna and who gave presentations on the clinical effectiveness and cost effectiveness of Naloxegol for treating opioid induced constipation.

12. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Naloxegol for treating opioid induced constipation 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 treatment pathway for people with opioid-induced constipation
    12.2. The most relevant comparator in the NHS
    12.3. The definition of laxative-inadequate response
    12.4. The generalisability of the naloxegol studies to the population of England with opioid-induced constipation and people
    12.5. The generalisability of the naloxegol studies to people with cancer pain who have opioid-induced constipation
    12.6. The results of the cost-effectiveness analysis presented by the company
    12.7. The ERG's critique of the company's cost-effectiveness analysis
    12.8. The ERG's exploratory analyses
    12.9. Whether naloxegol could be considered innovative in its potential to make a substantial effect on health-related benefits for people with opioid-induced constipation
    12.10. The Appraisal Committee considered whether it should take into account the consequences of PPRS 2014, and in particular the PPRS Payment Mechanism, when appraising naloxegol

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.

Commented [l1]: Use Chair's notes for information

17. The Committee continued to discuss the clinical and cost effectiveness of naloxegol for treating opioid-induced constipation.

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

Appraisal of Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia

Part 1 – Open session

19. The Chair welcomed company representatives from Roche Products to the meeting.

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

    20.1. Professor Kathryn Abel, Gail Coster, David Chandler,Professor Peter Crome, Professor Rachel Elliott, Dr Nigel Langford, Dr Claire McKenna, Dr Iain Miller, Professor Stephen O'Brien, Dr Anna O'Neill, Dr John Radford, Dr Peter Selby, Prof Matt Stevenson, 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 Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia

    20.2. Professor Stephen O'Brien declared a non-personal specific pecuniary interest as he is a member of the NCRI Clinical Studies Group (CSG) He has no involvement with trails, his involvement is CML. Non reimbursed postion.
    9.2.1 It was agreed that this declaration would not prevent Professor Stephen O'Brien from participating in this section of the meeting.

21. The Chair asked all NICE Staff to declare any 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 Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia.

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 Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia on the basis of the evidence before them. The discussions included:

    23.1. The clinical evidence from the CLL11 trial
    23.2. Consideration of comments from consultees in response to the ACD
    23.3. Consideration of any potential equality issues

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

28. The Committee continued to discuss the clinical and cost effectiveness of obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia.

29. 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

30. Tuesday 24 March 2015, 10:00 to 17:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.