

Technology Appraisal Committee Meeting (Committee B)

Minutes: **Confirmed**

Date and Time: Wednesday 6 July 2016, 10am to 4.30pm

Venue: Prospero House
241 Borough High Street
London
SE1 1GA

Present:	1. Dr Amanda Adler 2. Dr Sanjeev Patel 3. Dr Ray Armstrong 4. Dr Jeff Aronson 5. Professor John Cairns 6. Mark Chapman 7. Dr Mark Glover 8. Dr Neil Iosson 9. Dr Rebecca Kearney 10. Dr Sanjay Kinra 11. Professor Ruairidh Milne 12. Christopher O'Regan 13. Professor Stephen Palmer	Present for all notes Present for notes all notes Present for notes 1 to 16 Present for notes all notes Present for notes 1 to 29 Present for notes 1 to 16 as a Committee member and notes 17 to 27 and 30 to 39 as an Evidence Review Group representative
	14. Professor John Poundsford 15. Alun Roebuck 16. Dr Nigel De-Kare Silver 17. Marta Soares	Present for notes all notes Present for notes all notes Present for notes all notes Present for notes 1 to 16 and notes 30 to 42
	18. Professor Ken Stein 19. Dr Nicky Welton 20. Nigel Westwood	Present for notes all notes Present for notes all notes Present for notes all notes

In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Dr Melinda Goodall	Associate Director, National Institute for Health and Care Excellence	Present for all notes

Jeremy Powell	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Marcia Miller	Administrator, National Institute for Health and Care Excellence	Present for all notes
Irina Voicechovskaja	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 16
Rosie Lovett	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 16
Jasdeep Hayre	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 17 to 29
Raisa Sidhu	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 30 to 42
Professor James Mason	Professor of Health Economics, Warwick Evidence	Present for notes 1 to 14
Dr Emma Loveman	Warwick Evidence	Present for notes 1 to 14
Dr Edward Roddy	Clinical Senior Lecturer in Rheumatology and Honorary Consultant Rheumatologist, Keele University, clinical expert, nominated by the British Society for Rheumatology	Present for notes 1 to 14
Lynsey Conway	Secretariat, UK Gout Society, patient expert, nominated by the UK Gout Society	Present for notes 1 to 14
Nerys Woolacott	Senior Research Fellow, Centre for Reviews and Dissemination, University of York	Present for notes 17 to 27
Phil Morgan	Health Economist, Centre for Reviews and Dissemination, University of York	Present for notes 17 to 27
Dr Mary O'Brien	Consultant Medical Oncologist, Royal Marsden Hospital,	Present for notes 17 to 25

Dr Jesme Fox	clinical expert, nominated by Pfizer Medical Director, Roy Castle Lung Cancer Foundation, patient expert, nominated by the Roy Castle Lung Cancer Foundation	Present for notes 17 to 25
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Non-public observers:

Helen Barnett Mike Chambers	Medical Editor, NICE New member of Technology Appraisal Committee C	Present for all notes Present for all notes
Chloe Kastoryano	Public Involvement Adviser, Patient Involvement Programme, NICE	Present for notes 1 to 29
Heather Stegenga	Science policy and research programme team, NICE	Present for all notes
Thomas Wood	Technical Analyst, NICE	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 lesinurad for treating chronic hyperuricaemia in people with gout [ID761], crizotinib for untreated anaplastic lymphoma kinase-positive non-small-cell lung cancer [ID865] and apremilast moderate to severe - psoriasis (rapid review of TA368) [ID987].
2. The Chair informed the Committee that it was Dr Rebecca Kearney's last meeting as a Committee member and thanked her for her contributions to the Committee.
3. The Chair informed the Committee of the non-public observers at this meeting: Helen Barnett, Mike Chambers, Chloe Kastoryano, Heather Stegenga and Thomas Wood.
4. Apologies were received from Anne Joshua, Dr Miriam McCarthy and Dr Danielle Preedy,

Any other Business

5. The Committee were updated on changes to the Technology Appraisals for abiraterone for treating metastatic hormone-relapsed prostate cancer (TA387 and TA259), which were previously considered by this Committee. The Committee were informed that these guidance would be re-issued after a change to the commercial arrangements in July 2016. This reflected a change from the patient access scheme agreed with the Department of health to a confidential commercial access arrangement agreed with NHS England. The Committee were shown that it

had been verified by the Decision Support Unit and NICE that this did not impact cost effectiveness.

Appraisal of lesinurad for treating chronic hyperuricaemia in people with gout [ID761]

Part 1 – Open session

6. The Chair welcomed the invited experts: Professor James Mason, Dr Emma Loveman, Lynsey Conway and Dr Edward Roddy to the meeting and they introduced themselves to the Committee.
7. The Chair welcomed company representatives from AstraZeneca to the meeting.
8. The Chair asked all Committee members to declare any relevant interests
 - 8.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Dr Neil Iosson, Dr Rebecca Kearney, Dr Sanjay Kinra, Professor Ruairidh Milne, Mr Christopher O'Regan, Professor Stephen Palmer, Professor John Poundsford, Mr Alun Roebuck, Dr Nigel De-Kare Silver, Dr Marta Soares, Professor Ken Stein, Dr Nicky Welton and Mr Nigel Westwood all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 lesinurad for treating chronic hyperuricaemia in people with gout.
9. The Chair asked all NICE Staff to declare any relevant interests.
 - 9.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 lesinurad for treating chronic hyperuricaemia in people with gout.
10. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 10.1. Professor James Mason and Dr Emma Loveman, and Dr Edward Roddy declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 lesinurad for treating chronic hyperuricaemia in people with gout.
 - 10.2. Lynsey Conway declared a personal specific financial interest as she has acted as a corporate communications consultant for Grunenthal who are taking over the marketing authorisation of lesinurad.
 - 10.2.1. It was agreed that this declaration would not prevent Lynsey Conway from participating in this section of the meeting

- 10.3. Dr Edward Roddy declared a personal specific non-financial interest as he has acted as an advisor for the Evidence Review Group for this appraisal.
 - 10.3.1. It was agreed that this declaration would not prevent Dr Roddy from participating in this section of the meeting
11. The Chair introduced the lead team, Dr Neil Iosson, Professor Ruairidh Milne and Mr Nigel Westwood who gave presentations on the clinical effectiveness and cost effectiveness of lesinurad for treating chronic hyperuricaemia in people with gout.
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, Evidence Review Group representatives and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

15. The Committee continued to discuss the clinical and cost effectiveness of lesinurad for treating chronic hyperuricaemia in people with gout.
 - 15.1. The committee decision was based on consensus.
16. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of crizotinib for untreated anaplastic lymphoma kinase-positive non-small-cell lung cancer [ID865]

Part 1 – Open session

17. The Chair welcomed the invited experts: Nerys Woolacott, Professor Stephen Palmer, Phil Morgan, Dr Mary O'Brien and Dr Jesme Fox to the meeting and they introduced themselves to the Committee.
18. The Chair welcomed company representatives from Pfizer to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
 - 19.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Dr Neil Iosson, Dr Rebecca Kearney, Dr Sanjay Kinra, Professor Ruairidh Milne, Mr Christopher O'Regan, Professor John Poundsford, Mr Alun Roebuck, Dr Nigel De-Kare Silver, Professor Ken Stein and Mr Nigel Westwoodall declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 crizotinib for untreated anaplastic lymphoma kinase-positive non-small-cell lung cancer.

19.2. Dr Nicky Welton declared a non-personal non-specific financial interest as she is involved in a research project for which Pfizer provide funding for a research associate.
9.2.1. It was agreed that this declaration would not prevent Dr Welton from participating in this section of the meeting.

19.3. Dr Marta Soares declared a personal specific financial interest before the meeting as a family member is preparing a submission for Pfizer Portugal on crizotinib in this indication.
19.3.1. It was agreed that this declaration would prevent Dr Soares from participating in this section of the meeting.

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

20.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 crizotinib for untreated anaplastic lymphoma kinase-positive non-small-cell lung cancer.

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

21.1. Nerys Woolacott, Professor Stephen Palmer and Phil Morgan declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 crizotinib for untreated anaplastic lymphoma kinase-positive non-small-cell lung cancer.

21.2. Dr Mary O'Brien declared a personal specific financial interest as her husband holds shares in Pfizer and she has sat on advisory boards for a number of pharmaceutical companies.
21.2.1. It was agreed that this declaration would not prevent Dr O'Brien from participating in this section of the meeting

21.3. Dr Jesme Fox declared a non-personal non specific financial interest the Roy Castle Lung Cancer Foundation receives funding from Pfizer and other pharmaceutical companies. Dr Fox has also sat on advisory boards but has not received any payments personally.
21.3.1. It was agreed that this declaration would not prevent Dr Fox from participating in this section of the meeting

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

24. 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.
25. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

26. Discussion on confidential information continued. This information was supplied by the company.
27. The Evidence Review Group representatives left the meeting.
28. The Committee continued to discuss the clinical and cost effectiveness of crizotinib for untreated anaplastic lymphoma kinase-positive non-small-cell lung cancer.
 - 28.1. The committee decision was based on consensus.
29. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of apremilast moderate to severe - psoriasis (rapid review of TA368) [ID987]

Part 1 – Open session

30. The Chair welcomed the invited Evidence Review Group representative: Professor Stephen Palmer.
31. The Chair welcomed company representatives from Celgene to the meeting.
32. The Chair asked all Committee members to declare any relevant interests
 - 32.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Dr Neil Iosson, Dr Rebecca Kearney, Dr Sanjay Kinra, Professor Ruairidh Milne, Professor John Poundsford, Mr Alun Roebuck, Dr Nigel De-Kare Silver, Dr Marta Soares, Professor Ken Stein, Dr Nicky Welton and Mr Nigel Westwood all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 moderate to severe - psoriasis (rapid review of TA368).
 - 32.2. Mr Christopher O'Regan declared a personal specific financial interest before the meeting as he is employed by Merck Sharp and Dohme who are a comparator company in this appraisal.
 - 32.2.1. It was agreed that this declaration would prevent Mr O'Regan from participating in this section of the meeting.

33. The Chair asked all NICE Staff to declare any relevant interests.
 - 33.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 moderate to severe - psoriasis (rapid review of TA368).
34. The Chair asked Professor Stephen Palmer to declare any relevant interests.
 - 34.1. Professor Palmer declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 moderate to severe - psoriasis (rapid review of TA368).
35. The Chair gave a presentation summarising the Company's rapid review submission and the Evidence Review Group critique of that submission.
36. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
37. The Chair then thanked the company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

38. Discussion on confidential information continued. This information was supplied by the company.
39. The Evidence Review Group representatives left the meeting.
40. The Committee continued to discuss the clinical and cost effectiveness of apremilast moderate to severe - psoriasis (rapid review of TA368).
 - 40.1. The committee decision was based on consensus.
41. 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

42. Thursday 4 August 2016, 10am at the Royal College of General Practitioners, 30 Euston Square, London NW1 2FB