

Technology Appraisal Committee Meeting (Committee A)

Minutes: Confirmed

Date and Time: 27th October 2015

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

Present:		
1.	Dr Jane Adam	Present for all notes
2.	Professor Aileen Clarke	Present for all notes
3.	Dr Jeremy Braybrooke	Present for all notes
4.	Dr Brian Shine	Present for all notes
5.	Dr Justin Daniels	Present for all notes
6.	Dr Rachel Hobson	Present for all notes
7.	Dr Mohit Misra	Present for all notes
8.	Professor Olivia Wu	Present for all notes
9.	Dr John Watkins	Present for all notes
10.	Mr David Thomson	Present for all notes
11.	Ms Pamela Rees	Present for all notes
12.	Dr Graham Ash	Present for all notes
13.	Mr Stephen Sharp	Present for all notes
14.	Dr Nerys Woolacott	Present for all notes
15.	Mrs Sarah Parry	Present for all notes
16.	Dr Paul Robinson	Present for all notes
17.	Ellen Rule	Present for all notes
18.	Dr Eldon Spackman	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 Administrator, National Institute for Health and Care Excellence	Present for all notes
Helen Tucker	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 20 to 31
Zoe Charles	Technical Adviser, National Institute for Health and Clinical Excellence	Present for all notes
Assessment Group		
Samantha Barton	Evidence Team Lead	Present for all notes 1 to 19

Dr Steve Edwards	Head of Clinical and Economic Evidence	Present for all notes 1 to 19
ERG		
Susan Harnan	Research Fellow	Present for all notes 20 to 31
Paul Tappenden	Reader in Health Economics and Decision Science	Present for all notes 20 to 31
Clinical Experts		
Professor Charlie Gourley	Professor of Medical Oncology – clinical expert	Present for notes 20 to 31
Dr Simon Newman	Head of Research for Target Ovarian Cancer – patient expert	Present for all notes 20 to 31
Non-public observers:		
Sheela Upadhyaya	NICE, HST	Present for notes 1 - 19
Chloe Kastoryano	NICE, PPIP	Present for notes 1 to 19
Manisha Young	NICE, Corporate Office	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 topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (including reviews of technology appraisal guidance 91 and 222) and olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy [ID735]
2. The Chair welcomed Dr Justin Daniels and Dr Rachel Hobson to their first meeting as a member of the Appraisal Committee
3. The Chair informed the Committee of the non-public observers at this meeting:
4. Apologies were received from Dr Jeremy Braybrooke, Dr Gerardine Bryant, Dr Andrew England, Mr Adrian Griffin, Professor Iain Squire, Professor John McMurray and Dr Anne McCune
- 5.

Any other Business

6. None

Notes from the last meeting

7. The minutes were agreed.

Appraisal of MTA Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (including reviews of technology appraisal guidance 91 and 222)

Part 1 – Open session

8. The Chair welcomed the invited experts: Samantha Barton and Paul Tappenden to the meeting and they introduced themselves to the Committee.
9. The Chair welcomed company representatives from Phama Mar to the meeting.
10. The Chair asked all Committee members to declare any relevant interests
 - 10.1. **Dr Jane Adam, Professor Aileen Clarke , Dr Brian Shine Dr Justin Daniels, Dr Rachel Hobson, Dr Mohit Misra, Professor Olivia Wu , Dr John Watkins, Mr David Thomson, Ms Pamela Rees, Dr Graham Ash, Mr Stephen Sharp, Dr Nerys Woolacott, Mrs Sarah Parry , Dr Paul Robinson, Ellen Rule and Dr Eldon Spackman** 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 **topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (including reviews of technology appraisal guidance 91 and 222)**.
 - 10.2. Mr Adrian Griffin declared a non-personal specific financial interest as he is employed by Johnson and Johnson are a comparator company in the appraisal.
 - 9.2.1 It was agreed that this declaration would prevent Dr Adrian Griffin from participating in this section of the meeting.
11. The Chair asked all NICE Staff to declare any relevant interests.
 - 11.1. 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 **topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (including reviews of technology appraisal guidance 91 and 222)**.
12. The Chair asked all other invited guests, assessment group and invited experts, not including observers) to declare their relevant interests.
 - 12.1. 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 **topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (including reviews of technology appraisal guidance 91 and 222)**.
13. **The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (including reviews of technology appraisal guidance 91 and 222) 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:**
 - 13.2. Whether the recommendations for using PLDH in combination with carboplatin in the final appraisal determination issued to consultees and commentators before the appeal were appropriate

- 13.3. Clarifying and justifying the reasoning for its choice of appropriate dose regimens for different treatments and the costs used in the cost-effectiveness analyses
- 13.4. A discussion of the additional analyses produced by the Assessment Group after appeal showing the impact of varying the drug cost for paclitaxel and PLDH
14. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
15. 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.
16. 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

17. Discussion on confidential information continued. This information was supplied by the company.
18. The Committee continued to discuss the clinical and cost effectiveness of topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (including reviews of technology appraisal guidance 91 and 222).
19. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of Olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy [ID735]

Part 1 – Open session

20. The Chair welcomed the invited experts: Professor Charlie Gourley and Dr Simon Newman to the meeting and they introduced themselves to the Committee.
21. The Chair welcomed company representatives from **AstraZeneca** to the meeting.
22. The Chair asked all Committee members to declare any relevant interests
 - 22.1. **Dr Jane Adam, Professor Aileen Clarke , Dr Brian Shine Dr Justin Daniels, Dr Rachel Hobson, Dr Mohit Misra, Professor Olivia Wu , Dr John Watkins, Mr David Thomson, Ms Pamela Rees, Dr Graham Ash, Mr Stephen Sharp, Dr Nerys Woolacott, Mrs Sarah Parry , Dr Paul Robinson, Ellen Rule and Dr Eldon Spackman** 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 olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy.

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

23.1. 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 olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy

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

24.1. 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 olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy.

1.1. Professor Charlie Gourley declared a non-personal specific financial interest as Personal and non-personal specific and non-specific interests in AstraZeneca and Roche. Personal and non-personal non-specific interests in GlaxoSmithKline.

1.2.

9.2.1 It was agreed that this declaration would not prevent Professor Charlie Gourley from participating in this section of the meeting.

25. 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.

26. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy [ID735] 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:

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

26.2. The clinical evidence for the subgroup of patients in Study 19 who received 3 or more lines of platinum-based chemotherapy

26.3. The results of the company's cost effectiveness analyses using a 4 health state model and a 3 health state model for the subgroup of patients who received 3 or more lines of platinum-based of chemotherapy, which incorporated a revised patient access scheme

26.4. Whether the end-of-life criteria would apply to the subgroup of patients with BRCA mutation-positive disease in Study 19 who had received 3 or more previous lines of platinum-based chemotherapy

27. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
28. 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.
29. 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

30. Discussion on confidential information continued. This information was supplied by the company.
 - 30.1. The Committee continued to discuss the clinical and cost effectiveness of olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy on the basis of the evidence before them, and potential equality issues raised in this appraisal
31. 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

32. Wednesday 25th November 2015, at Prospero House, 241 Borough High Street, London SE1 1GA.