Technology Appraisal Committee Meeting (Committee A)

National Institute for Health and Care Excellence, 10 Spring Gardens, London SW1A 2BU

Minutes: Confirmed

Date and Time: Tuesday 12 March 2019, 10:00 – 15:00

Present:

1. Dr Jane Adam (Chair) Present for all notes
2. Dr Brian Shine (Vice-Chair) Present for all notes
3. Dr Graham Ash Present for all notes
4. Dr Jeremy Braybrooke Present for all notes
5. Dr Justin Daniels Present for all notes
6. Dr Steve Edwards Present for notes 11 to 15
7. Mr Adrian Griffin Present for notes 1 to 10
8. Dr Mohit Sharma Present for all notes
9. Mr Stephen Sharp Present for all notes
10. Dr Alice Turner Present for all notes
11. Dr Mark Upton Present for all notes
12. Mrs Sarah Parry Present for all notes
13. Professor Olivia Wu Present for all notes
14. Ms Pamela Rees Present for all notes
15. Dr Paul Robinson Present for notes 1 to 10
16. Dr Roger Whittaker Present for all notes
17. Dr Sumithra Maheswaran Present for all notes
18. Mr Min Ven Teo Present for notes 11 to 15

In attendance:

- Helen Knight 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
- Thomas Feist Project Manager, National Institute for Health and Care Excellence Present for all notes
- Marcia Miller Technology Administrator, Present for all notes
- Marcela Haasova Technology Appraisal Technical Analyst, Present for notes 1 to 10
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<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Present for Notes</th>
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<tbody>
<tr>
<td>Joanna Richardson</td>
<td>Technology Appraisal Technical Advisor</td>
<td>1 to 10</td>
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<tr>
<td>Thomas Strong</td>
<td>Technology Appraisal, CDF HTA Advisor</td>
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<tr>
<td>Sana Khan</td>
<td>Technology Appraisal Technical Analyst</td>
<td>11 to 15</td>
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<td>Zoe Charles</td>
<td>Technology Appraisal Technical Advisor</td>
<td>11 to 15</td>
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<tr>
<td>Dr Steve Edwards</td>
<td>Evidence Review Group, Director of Health Technology Appraisals (BMJ)</td>
<td>1 to 7</td>
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<tr>
<td>Dr Samantha Barton</td>
<td>Evidence Review Group, Senior Research Fellow, Health Technology Appraisals (BMJ)</td>
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<td>Dr Peter Cain</td>
<td>Evidence Review Group, Senior Research Fellow, Health Technology Appraisals (BMJ)</td>
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<td>Professor Peter Clark</td>
<td>NHS England, CDF Clinical Lead</td>
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<tr>
<td>Ms Holly Heath</td>
<td>Patient expert</td>
<td>1 to 7</td>
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<td>Professor Robert Thomas</td>
<td>Clinical expert</td>
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<td>Karen Ang</td>
<td>NICE, Scientific Advice</td>
<td>1 to 10</td>
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<td>Ana Uribe Echeverry</td>
<td>NICE, Corporate Office</td>
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<td>Mr Tony Heddon</td>
<td>NICE, Lay member appeal panel member</td>
<td>1 to 10</td>
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<tr>
<td>Adam Storrow</td>
<td>NICE, Resource Impact Assessment</td>
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<tr>
<td>Ria Skelton</td>
<td>NICE, Appraisal Editors</td>
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Notes
Minutes from the last meeting

1. The committee approved the minutes of the committee meeting held on Tuesday 8 January 2019.

Appraisal of Ribociclib in combination with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer [ID1318]

Part 1 – Open session

2. The Chair welcomed the invited clinical and patient experts, Evidence Review Group (ERG) and representatives from Novartis.

3. The Chair asked all committee members, experts, ERG representatives and NICE staff present to declare any relevant interests.

   3.1. Dr Jeremy Braybrooke declared a non-financial interest as he has been a co-investigator on clinical trials with ribociclib and palbociclib in breast cancer.
   3.1.1. It was agreed that the declaration of interest made would not prohibit Dr Jeremy Braybrooke from participating in this appraisal.

   3.2. Ms Holly Heath declared a direct financial interest as Breast Cancer Now has received some funding from Novartis and other pharmaceutical companies involved in this appraisal (details are listed on their website). Breast Cancer Now does not receive funding for work on access to treatment.
   3.2.1. It was agreed that the declaration of interests made would not prohibit Ms Holly Heath from participating in this appraisal.

   3.3. Dr Steve Edwards did not take part as a member of the Committee as he was participating as a member of the Evidence Review Group.

4. The Chair introduced the lead team, Dr Paul Robinson, Mr Stephen Sharp and Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Ribociclib in combination with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer.

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

6. 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.

7. The Chair then thanked the and company representatives, evidence review group and experts for their attendance, participation and contribution to the appraisal and they left the meeting.
Part 2 – Closed session

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

9. The Committee continued to discuss the clinical and cost effectiveness.
   9.1. The committee decision was based on consensus.

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

Appraisal of Ertugliflozin in a triple therapy regimen for treating type 2 diabetes [ID1160]

Part 1 – Open session

11. The Chair welcomed the company representatives from Merck Sharp and Dohme to the meeting.

12. The Chair asked all Committee members to declare any relevant interests
   12.1. Mr Adrian Griffin declared a direct financial interest as he is employed by Johnson and Johnson who own a comparator drug in this appraisal.
          12.1.1. It was agreed that the declaration of interests made would prohibit Mr Adrian Griffin from participating in this appraisal and he remained absent from the meeting.

   12.2. Professor John McMurray declared a indirect financial interest as he is a principal/co-principal investigator for two international trials, testing the efficacy and safety of dapagliflozin (AstraZeneca) in heart failure and another using bexagliflozin (Theracos) in patients with type 2 diabetes and cardiovascular disease or cardiovascular risk factors. He is also one of a group of lead investigators for local trials using empagliflozin (Boehringer Ingelheim) in patients with type 2 diabetes and heart failure.
          12.2.1. It was agreed that the declaration of interests made would prohibit Professor John McMurray from participating in this appraisal and he remained absent from the meeting.

   12.3. Dr Paul Robinson declared a direct financial interest as he is employed by the company of the technology.
          12.3.1. It was agreed that the declaration of interests made would prohibit Dr Paul Robinson from participating in this appraisal he remained absent from the meeting.

13. The Chair asked all NICE Staff to declare any relevant interests.
   13.1. No declaration of interests were made in relation to this topic

14. The Chair gave a presentation on the new information provided by the company.

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

Date, time and venue of the next meeting

16. Tuesday 9 April 2019, 10am at National Institute for Health and Care Excellence, 10 Spring Gardens, London SW1A 2BU