Technology Appraisal Committee Meeting (Committee C)

Minutes:  Confirmed

Date and Time:  Wednesday 11 May, 10:00 to 14:30

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

Present:  1. Chair Professor Andrew Stevens  Present for all notes
          2. Professor Kathryn Abel  Present for all notes
          3. Dr Ian Bernstein  Present for all notes
          4. David Chandler  Present for all notes
          5. Professor Rachel Elliott  Present for all notes
          6. Dr Nigel Langford  Present for all notes
          7. Professor Andrea Manca  Present for all notes
          8. Dr Iain Miller  Present for all notes
          9. Dr Paul Miller  Present for all notes
         10. Professor Stephen O’Brien  Present for all notes
         11. Dr Anna O’Neill  Present for all notes
         12. Professor Andrew Renehan  Present for all notes
         13. Dr Peter Selby  Present for all notes
         14. Prof Matt Stevenson  Present for all notes
         15. Dr Paul Tappenden  Present for all notes
         16. Dr Judith Wardle  Present for all notes

In attendance:

Meindert Boysen  Programme Director, National Institute for Health and Care Excellence  Present for all notes

Dr Frances Sutcliffe  Associate Director, National Institute for Health and Care Excellence  Present for all notes

Stephanie Yates  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
<table>
<thead>
<tr>
<th>Name</th>
<th>Role/Position</th>
<th>Present for</th>
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<tbody>
<tr>
<td>Henry Edwards</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>04 to 08</td>
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<tr>
<td>Joanne Holden</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>04 to 08</td>
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<tr>
<td>Stuart Wood</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>09 to 12</td>
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<tr>
<td>Nicola Hay</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>09 to 12</td>
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<td>Non-public observers:</td>
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<tr>
<td>Ewen Cummins</td>
<td>ERG representative</td>
<td>04 to 07</td>
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<tr>
<td>Neil Scott</td>
<td>ERG representative</td>
<td>04 to 07</td>
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<tr>
<td>Noemi Lois</td>
<td>ERG representative</td>
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<tr>
<td>Ruben Mujica-Mota</td>
<td>ERG representative</td>
<td>04 to 07</td>
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<td>Irina Tikhonova</td>
<td>ERG representative</td>
<td>04 to 07</td>
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<tr>
<td>Dr Ian Pearce</td>
<td>Clinical Expert</td>
<td>04 to 07</td>
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<tr>
<td>Dr Winfred Amoaku</td>
<td>Clinical Expert</td>
<td>04 to 07</td>
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<td>Professor Subbiyan</td>
<td>Patient Expert</td>
<td>04 to 07</td>
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<tr>
<td>Rajendran</td>
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<td>Mrs Melba Ryde</td>
<td>Patient Expert</td>
<td>04 to 08</td>
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<td>Gabriel Rogers</td>
<td>NICE Observer</td>
<td>04 to 08</td>
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<td>Gemma Smith</td>
<td>NICE Observer</td>
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<td>Kate Moring</td>
<td>NICE Observer</td>
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<tr>
<td>Sam Parker</td>
<td>NICE Observer</td>
<td>04 to 08</td>
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<tr>
<td>Stephanie Birtles</td>
<td>NICE Observer</td>
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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 aflibercept for treating visual impairment caused by macular oedema in branch retinal vein occlusion and azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts.

2. Apologies were received from Professor Eugene Milne, Gail Coster and Dr Robert Walton.

Any other Business

3. None

Appraisal of aflibercept for treating visual impairment caused by macular oedema in branch retinal vein occlusion

Part 1 – Open session

4. The Chair welcomed the invited experts: Dr Ian Pearce, Dr Winfred Amoaku, Professor Subbiyan Rajendran and Mrs Melba Ryde to the meeting and they introduced themselves to the Committee.

5. The Chair welcomed company representatives from Bayer to the meeting.

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

6.1. Professor Kathryn Abel, Dr Ian Bernstein, David Chandler, Professor Rachel Elliott, Dr Nigel Langford, Professor Andrea Manca, Dr Iain Miller, Dr Paul Miller, Professor Stephen O’Brien, Dr Anna O’Neill, Professor Andrew Renehan, Dr Peter Selby, Prof Matt Stevenson, Dr Paul Tappenden and Dr Judith Wardle 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 aflibercept for treating visual impairment caused by macular oedema in branch retinal vein occlusion.

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

7.1. 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 aflibercept for treating visual impairment caused by macular oedema in branch retinal vein occlusion.

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

8.1. 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 aflibercept for treating visual impairment caused by macular oedema in branch retinal vein occlusion.

8.2. Dr Ian Pearce declared a personal non-specific financial interest as he has received consultancy and lecture fees from Bayer and Allegan.

8.2.1. It was agreed that this declaration would not prevent Dr Ian Pearce from participating in this section of the meeting.

8.3. Dr Winfred Amoaku declared a personal non-specific financial interest as he has received consultancy fees from Bayer, Allegan, Novartis and Pfizer.

8.3.1. It was agreed that this declaration would not prevent Dr Winfred Amoaku from participating in this section of the meeting.

9. The Chair introduced the lead team, Dr Andrea Manca, Professor Kathryn Abel and David Chandler who gave presentations on the clinical effectiveness and cost effectiveness of aflibercept for treating visual impairment caused by macular oedema in branch retinal vein occlusion.

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

11. 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.

12. 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

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

14. The Committee continued to discuss the clinical and cost effectiveness of aflibercept for treating visual impairment caused by macular oedema in branch retinal vein occlusion.

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

Appraisal of azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts

Part 1 – Open session

16. The Chair welcomed company representatives from Celgene to the meeting.

17. The Chair asked all Committee members to declare any relevant interests.
17.1. Professor Kathryn Abel, Dr Ian Bernstein, David Chandler
Professor Rachel Elliott, Dr Nigel Langford, Professor Andrea Manca
Dr Iain Miller, Dr Paul Miller, Professor Stephen O’Brien, Dr Anna O’Neill
Professor Andrew Renehan, Dr Peter Selby, Prof Matt Stevenson
Dr Paul Tappenden and Dr Judith Wardle 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 azacitidine for treating acute myeloid
leukaemia with more than 30% bone marrow blasts.

17.2. Professor Stephen O’Brien declared a non-personal specific non specific
financial. He is a member of the NCRI Clinical Studies Group (CSG),
which oversees a portfolio of leukaemia trials in the UK. I have no current
involvement with CLL trials – my involvement is in CML. Non-reimbursed
position.
9.2.1 It was agreed that this declaration would not prevent
Professor Stephen O’Brien from participating in this section of the
meeting.

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

18.1. 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 azacitidine for
treating acute myeloid leukaemia with more than 30% bone marrow
blasts.

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

19.1. 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 azacitidine for
treating acute myeloid leukaemia with more than 30% bone marrow
blasts.

20. 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.

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

22. 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.
23. 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

24. The Committee continued to discuss the clinical and cost effectiveness of azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts

25. 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

26. Wednesday 15 June 2016, 10:00 to 17:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT