Technology Appraisal Committee Meeting (Committee D)

Minutes: Confirmed

Date and Time: Tuesday 28 February 2017 10am – 5pm

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

Present:
1. Professor Gary McVeigh (Chair) Present for all notes
2. Dr Lindsay Smith (Vice Chair) Present for all notes
3. Dr Andrew Black Present for all notes
4. Dr Matthew Bradley Present for all notes
5. Dr Ian Davidson Present for all notes
6. Professor Simon Dixon Present for all notes
7. Susan Dutton Present for all notes
8. Gillian Ells Present for all notes
9. Sumithra Maheswaran Present for all notes
10. Professor David Meads Present for all notes
11. Dr Malcolm Oswald Present for all notes
12. Professor Femi Oyebode Present for all notes
13. Pamela Rees Present for all notes
14. Professor Paul Tappenden Present for notes 16 to 48

In attendance:

Dr Nigel Armstrong Health Economist, Kleijnen Systematic Reviews (KSR) Present for notes 28 to 35

Orsolya Balogh Technical Analyst, National Institute for Health and Care Excellence Present for notes 1 to 15

Catherine Bouvier Patient expert, nominated by the NET Patient Foundation Present for notes 16 to 24

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

Professor Peter Clark CDF Clinical lead, NHS England Present for notes 16 to 38

Dr Sally Doss Technical Adviser, National Institute for Health and Clinical Excellence Present for notes 1 to 15
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Present for notes</th>
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<tbody>
<tr>
<td>Dr Martin Eatock</td>
<td>Consultant Medical Oncologist, Clinical expert nominated by Pfizer</td>
<td>16 to 24</td>
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<tr>
<td>Ed Griffin</td>
<td>Associate Research Fellow, Peninsula Technology Assessment Group (PenTAG)</td>
<td>16 to 24</td>
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<tr>
<td>Sana Khan</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>28 to 38</td>
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<tr>
<td>Helen Knight</td>
<td>Associate Director, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<td>Fay McCracken</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>39 to 48</td>
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<tr>
<td>Kate Moore</td>
<td>Project Manager, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<tr>
<td>Dr Ruben Mujica Mota</td>
<td>Senior Lecturer in Health Economics, Peninsula Technology Assessment Group (PenTAG)</td>
<td>16 to 24</td>
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<td>Professor Paul Tappenden</td>
<td>Decision Support Unit representative</td>
<td>1 to 12</td>
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<td>Aminata Thiam</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>39 to 48</td>
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<td>Dr Irina Tikhonova</td>
<td>Research Fellow, Peninsula Technology Assessment Group (PenTAG)</td>
<td>16 to 24</td>
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<td>Nwamaka Umeweni</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>16 to 38</td>
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<td>Professor Juan Valle</td>
<td>Professor of Medical Oncology, Clinical expert nominated by the Royal</td>
<td>16 to 24</td>
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<td>Position</td>
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<tr>
<td>Jo Varley-Campbell</td>
<td>Associate Research Fellow, Peninsula Technology Assessment Group (PenTAG)</td>
<td>16 to 24</td>
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<tr>
<td>Mark Zwanziger</td>
<td>Patient expert, nominated by the NET Patient Foundation</td>
<td>16 to 24</td>
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<td><strong>Non-public observers:</strong></td>
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<td>Ann Greenwood</td>
<td>Senior Medical Editor, National Institute for Health and Clinical Excellence</td>
<td>1 to 48</td>
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<tr>
<td>Peter Hall</td>
<td>New Technology Appraisal Committee D member</td>
<td>1 to 48</td>
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<td>Rebecca Harmston</td>
<td>New Technology Appraisal Committee D member</td>
<td>1 to 48</td>
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<td>Sarah Richards</td>
<td>Health Economist, National Institute for Health and Clinical Excellence</td>
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<td>Hayley Sharp</td>
<td>Senior Medical Editor, National Institute for Health and Clinical Excellence</td>
<td>1 to 48</td>
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<td>Lydia Shears</td>
<td>Public Involvement Adviser, National Institute for Health and Clinical Excellence</td>
<td>16 to 24</td>
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<tr>
<td>Maroulla Whitely</td>
<td>Business Analyst, National Institute for Health and Clinical Excellence</td>
<td>1 to 48</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 collagenase clostridium histolyticum for treating Dupuytren’s contracture, everolimus, lutetium-177 DOTATATE and sunitinib for
treating unresectable or metastatic neuroendocrine tumours with disease progression, nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy, and certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.

2. The Chair informed the Committee of the non-public observers at this meeting.

3. Apologies were received from Professor David Bowen, Professor Rachel Elliott, Professor Paula Ghaneh and Dr Paula Parvulescu.

Any other Business

4. None

Appraisal of collagenase clostridium histolyticum for treating Dupuytren’s contracture

Part 2a – Closed session

5. The Chair welcomed the invited experts: Professor Paul Tappenden to the meeting and they introduced themselves to the Committee.

6. The Chair welcomed company representatives from Swedish Orphan Biovitrium to the meeting.

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

7.1. Dr Andrew Black, Dr Matthew Bradley, Dr Ian Davidson, Professor Simon Dixon, Susan Dutton, Gillian Ells, Sumithra Maheswaran, Professor Gary McVeigh, Professor David Meads, Dr Malcolm Oswald, Professor Femi Oyebode, Dr Lindsay Smith and Pam Rees 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 collagenase clostridium histolyticum for treating Dupuytren’s contracture.

8. The Chair asked all NICE Staff to declare any 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 collagenase clostridium histolyticum for treating Dupuytren’s contracture.

9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their 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 collagenase clostridium histolyticum for treating Dupuytren’s contracture.

10. The Chair provided the background to the appraisal and the additional evidence provided by the company.

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

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 2b – 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 collagenase clostridium histolyticum for treating Dupuytren’s contracture.

14.1. A vote was taken. The options were:
Option 1: To recommend the technology under specific conditions
Option 2: Not to recommend the technology under specific conditions
The Committee voted for Option 1

15. The Committee instructed the technical team to prepare the Final Appraisal Determination in line with their decisions.

Appraisal of everolimus, lutetium-177 DOTATATE and sunitinib for treating unresectable or metastatic neuroendocrine tumours with disease progression

Part 1 – Open session

16. The Chair welcomed the invited experts: Catherine Bouvier, Professor Peter Clark, Dr Martin Eatock, Ed Griffin, Dr Ruben Mujica Mota, Dr Irina Tikhonova, Professor Juan Valle, Jo Varley-Campbell, and Mark Zwanziger to the meeting and they introduced themselves to the Committee.

17. The Chair welcomed company representatives from AAA, Novartis and Pfizer to the meeting.

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

18.1. Dr Andrew Black, Dr Matthew Bradley, Dr Ian Davidson, Susan Dutton, Gillian Ells, Sumithra Maheswaran, Professor Gary McVeigh, Professor David Meads, Dr Malcolm Oswald, Professor Femi Oyebode, Dr Lindsay Smith, Pam Rees and Professor Paul Tappenden 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 everolimus, lutetium-177 DOTATATE and sunitinib for treating unresectable or metastatic neuroendocrine tumours with disease progression.
18.2. Professor Simon Dixon declared a non-personal non-specific financial interest as he is the Director of a Health Economics Unit that has undertaken work for some of the companies involved in the appraisal, but on unrelated topics. Professor Dixon was not involved in the work and did not receive personal payment for it.

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

19. The Chair asked all NICE Staff to declare any 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 everolimus, lutetium-177 DOTATATE and sunitinib for treating unresectable or metastatic neuroendocrine tumours with disease progression.

20. The Chair asked all other invited guests to declare their 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 everolimus, lutetium-177 DOTATATE and sunitinib for treating unresectable or metastatic neuroendocrine tumours with disease progression.

21. The Chair introduced the lead team, Dr Ian Davidson, Pam Rees and Gillian Ells, who gave presentations on the clinical effectiveness and cost effectiveness of everolimus, lutetium-177 DOTATATE and sunitinib for treating unresectable or metastatic neuroendocrine tumours with disease progression.

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

23. 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.

24. 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

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

26. The Committee continued to discuss the clinical and cost effectiveness of everolimus, lutetium-177 DOTATATE and sunitinib for treating unresectable or metastatic neuroendocrine tumours with disease progression.
26.1. The committee decision was based on consensus.

27. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy

Part 2a – Closed session

28. The Chair welcomed the invited experts, Dr Nigel Armstrong and Professor Peter Clark, to the meeting and they introduced themselves to the Committee.

29. The Chair welcomed company representatives from Bristol Myers-Squibb to the meeting.

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

30.1. Dr Andrew Black, Dr Matthew Bradley, Dr Ian Davidson, Susan Dutton, Gillian Ells, Sumithra Maheswaran, Professor Gary McVeigh, Professor David Meads, Dr Malcolm Oswald, Professor Femi Oyebode, Dr Lindsay Smith, Pam Rees and Professor Paul Tappenden 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 nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy.

30.2. Professor Simon Dixon declared a non-personal non-specific financial interest as he is the Director of a Health Economics Unit that has undertaken work for some of the companies involved in the appraisal, but on unrelated topics. Professor Dixon was not involved in the work and did not receive personal payment for it. 9.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.

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

31.1. 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 nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy.

32. The Chair asked all other invited guests to declare their relevant interests.

32.1. 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 nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy.

33. The Chair provided the background to the appraisal and the additional evidence provided by the company.

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

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

Part 2b – Closed session

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

37. The Committee continued to discuss the clinical and cost effectiveness of nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy.

37.1. The committee decision was based on consensus.

38. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs

Part 1 – Open session

39. The Chair welcomed company representatives from Novartis and UCB Pharma to the meeting.

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

40.1. Dr Matthew Bradley, Dr Ian Davidson, Susan Dutton, Gillian Ells, Sumithra Maheswaran, Professor Gary McVeigh, Professor David Meads, Dr Malcolm Oswald, Professor Femi Oyebode, Dr Lindsay Smith, Pam Rees and Professor Paul Tappenden 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 certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.

40.2. Professor Simon Dixon declared a non-personal non-specific financial interest as he is the Director of a Health Economics Unit that has undertaken work for some of the companies involved in the appraisal, but
on unrelated topics. Professor Dixon was not involved in the work and did not receive personal payment for it.

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

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

41.1. 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 certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.

42. 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.

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

44. 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.

45. 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

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

47. The Committee continued to discuss the clinical and cost effectiveness of certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs.

47.1. The committee decision was based on consensus.

48. 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

49. Wednesday 29 March 2017 10am – 5pm at the National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.