Technology Appraisal Committee Meeting (Committee B)

Minutes: Confirmed

Date and Time: Thursday 20 April 2017, 10am to 5pm

Venue: National Institute for Health and Care Excellence
10 Spring Gardens, London, SW1A 2BU, United Kingdom

Present:
1. Dr Amanda Adler (Chair) Present for all notes
2. Dr Sanjeev Patel (Vice-Chair) Present for all notes
3. Professor John Cairns Present for all notes
4. Mr Mark Chapman Present for all notes
5. Dr Mark Glover Present for all notes
6. Mrs Anne Joshua Present for all notes
7. Dr Sanjay Kinra Present for all notes
8. Dr Miriam McCarthy Present for notes 1 to 48
9. Mr Christopher O'Regan Present for notes 1 to 30 and notes 42 to 51
10. Dr Danielle Preedy Present for all notes
11. Dr Nicky Welton Present for all notes
12. Mr Nigel Westwood Present for all notes
13. Dr Stuart Williams Present for 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

Bashama Anjum Administrator, National Institute for Health and Care Excellence Present for all notes

Jasdeep Hayre Technical Adviser, National Institute for Health and Clinical Excellence Present for notes 1 to 17 and notes 31 to 41

Ahmed Elsada Technical Adviser, National Institute for Present for notes 18 to 30
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Present for notes</th>
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<tbody>
<tr>
<td>Thomas Paling</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>1 to 17</td>
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<td>Jessica Maloney</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>18 to 30</td>
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<td>Aimely Lee</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>31 to 41</td>
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<td>Sophie Cooper</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>42 to 51</td>
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<tr>
<td>Dr Edward Roddy</td>
<td>Clinical Senior Lecturer in Rheumatology and Honorary Consultant Rheumatologist, Keele University, clinical expert nominated by the British Society for Rheumatology</td>
<td>7 to 15</td>
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<tr>
<td>Lynsey Conway</td>
<td>Secretariat, UK Gout Society, patient expert nominated by the UK Gout Society</td>
<td>7 to 15</td>
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<td>Professor James Mason</td>
<td>Professor of Health Economics, Warwick Evidence</td>
<td>7 to 15</td>
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<tr>
<td>Mariana Bacelar</td>
<td>Senior Health Economist, BMJ Technology Assessment Group</td>
<td>18 to 28</td>
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<tr>
<td>Samantha Barton</td>
<td>Evidence Team Lead, BMJ Technology Assessment Group</td>
<td>18 to 28</td>
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<tr>
<td>Dr Steve Edwards</td>
<td>Head of Clinical &amp; Economic Evidence, BMJ Technology Assessment Group</td>
<td>18 to 28</td>
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<tr>
<td>Dr Claire Rothery</td>
<td>Senior Research Fellow, Centre for Reviews and Dissemination / Centre for Health Economics, University of York</td>
<td>31 to 39</td>
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**Non-public observers:**

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<th>Name</th>
<th>Position</th>
<th>Present for notes</th>
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<tr>
<td>Dr Elisabeth George</td>
<td>Associate Director, National Institute for Health and Care Excellence</td>
<td>1 to 17</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 lesinurad for treating chronic hyperuricaemia in people with gout [ID761], daratumumab monotherapy for treating relapsed and refractory multiple myeloma [ID933], adalimumab, etanercept and ustekinumab for treating severe, chronic plaque psoriasis in children and young people [ID854] and pirfenidone for treating idiopathic pulmonary fibrosis (review of TA282) [ID837].

2. The Chair informed the Committee that this was Anne Joshua’s last meeting and thanked her for her contributions to the Committee.

3. The Chair informed the Committee of the non-public observers at this meeting: Dr Elisabeth George and Edgar Masanga.

4. Apologies were received from Dr Ray Armstrong, Dr Sumeet Gupta, Dr Neil Iosson, Dr Nigel De Kare Silver, Professor Stephen Palmer, Ms Marta Soares and Professor Ken Stein.

Any other Business

5. The Committee were given an update on the timelines for other appraisals.

Notes from the last meeting

6. The minutes of the meetings held on 22 February 2017 and 23 March 2017 were approved.

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

Part 1 – Open session

7. The Chair welcomed the invited experts: Lynsey Conway, Dr Edward Roddy and Professor James Mason to the meeting and they introduced themselves to the Committee.

8. The Chair welcomed company representatives from Grunenthal to the meeting.

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

9.1. Dr Amanda Adler, Dr Sanjeev Patel, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Mr Christopher O'Regan, Dr Danielle Preedy, Dr Nicky
Welton, Mr Nigel Westwood and Dr Stuart Williams 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 [ID761].

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

10.1. 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 [ID761].

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

11.1. Professor James Mason declared that he 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 [ID761].

11.2. Lynsey Conway declared a personal specific interest as the UK Gout Society has received funding from pharmaceutical companies for a Parliamentary reception.

11.2.1. It was agreed that this declaration would not prevent Ms Conway from participating in this section of the meeting

11.3. Dr Edward Roddy declared a personal specific interest as he has provided expert advice to the Evidence Review Group for this appraisal.

11.3.1. It was agreed that this declaration would not prevent Ms Conway from participating in this section of the meeting

12. 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.

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

14. 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.

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

Part 2 – Closed session
16. The Committee continued to discuss the clinical and cost effectiveness of lesinurad for treating chronic hyperuricaemia in people with gout [ID761].

16.1. The committee decision was based on consensus.

17. 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 daratumumab monotherapy for treating relapsed and refractory multiple myeloma [ID933]**

**Part 1 – Open session**

18. The Chair welcomed the invited experts: Mariana Bacelar, Samantha Barton and Dr Steve Edwards to the meeting and they introduced themselves to the Committee.

19. The Chair welcomed company representatives from Janssen to the meeting.

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

20.1. Dr Amanda Adler, Dr Sanjeev Patel, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Mr Christopher O'Regan, Dr Danielle Preedy, Dr Nicky Welton, Mr Nigel Westwood and Dr Stuart Williams 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 daratumumab monotherapy for treating relapsed and refractory multiple myeloma [ID933].

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

21.1. 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 daratumumab monotherapy for treating relapsed and refractory multiple myeloma [ID933].

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

22.1. 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 daratumumab monotherapy for treating relapsed and refractory multiple myeloma [ID933].
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.

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

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.

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

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

The Chair then thanked the Evidence Review Group representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

The Committee continued to discuss the clinical and cost effectiveness of daratumumab monotherapy for treating relapsed and refractory multiple myeloma [ID933].

29.1. The committee decision was based on consensus.

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

Appraisal of adalimumab, etanercept and ustekinumab for treating severe, chronic plaque psoriasis in children and young people [ID854]

Part 1 – Open session

The Chair welcomed the invited expert: Dr Claire Rothery to the meeting and she introduced herself to the Committee.

The Chair welcomed company representatives from AbbVie and Janssen to the meeting.

The Chair asked all Committee members to declare any relevant interests

33.1. Dr Amanda Adler, Dr Sanjeev Patel, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Dr Danielle Preedy, Mr Nigel Westwood and Dr Stuart Williams 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 adalimumab, etanercept and ustekinumab for treating severe, chronic plaque psoriasis in children and young people [ID854].

33.2. Dr Nicky Welton declared a non-personal specific financial interest as she is working on a methodology project on pain relief which receives funding from Pfizer for a researcher.

9.3.1 It was agreed that this declaration would not prevent Dr Welton from participating in this section of the meeting.

33.3. Mr Christopher O'Regan declared a personal specific financial interest before the meeting as he is employed by Merck Sharp and Dohme.

9.2.1 It was agreed before the meeting that this declaration would prevent Mr O'Regan from participating in this section of the meeting.

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

34.1. 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 adalimumab, etanercept and ustekinumab for treating severe, chronic plaque psoriasis in children and young people [ID854].

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

35.1. Dr Claire Rothery declared that she 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 adalimumab, etanercept and ustekinumab for treating severe, chronic plaque psoriasis in children and young people [ID854].

36. The Vice-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.

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

38. The Vice-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.

39. The Vice-Chair then thanked the experts Assessment Group and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session
40. The Committee continued to discuss the clinical and cost effectiveness of adalimumab, etanercept and ustekinumab for treating severe, chronic plaque psoriasis in children and young people [ID854].

40.1. The committee decision was based on consensus.

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

Appraisal of pirfenidone for treating idiopathic pulmonary fibrosis (review of TA282) [ID837]

Part 1 – Open session

42. The Chair welcomed company representatives from Roche to the meeting.

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

43.1. Dr Amanda Adler, Dr Sanjeev Patel, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Mr Christopher O'Regan, Dr Danielle Preedy, Dr Nicky Welton, Mr Nigel Westwood and Dr Stuart Williams 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 pirfenidone for treating idiopathic pulmonary fibrosis (review of TA282) [ID837].

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

44.1. 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 pirfenidone for treating idiopathic pulmonary fibrosis (review of TA282) [ID837].

45. The Chair introduced the key issues to be considered by the Committee following the appeal.

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

47. 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.

48. 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
49. Discussion on confidential information continued. This information was supplied by the company.

50. The Committee continued to discuss the clinical and cost effectiveness of pirfenidone for treating idiopathic pulmonary fibrosis (review of TA282) [ID837].

50.1. The committee decision was based on consensus.

51. 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**

52. Tuesday 23 May 2017, 10am to 5pm at ETC venues, Prospero House, 241 Borough High Street, London SE1 1GA.