

## Technology Appraisal Committee Meeting (Committee A)

**Minutes:** Confirmed

**Date and Time:** 25<sup>th</sup> February 2015

**Venue:** Royal College of General Practitioners, 30 Euston Square, London, NW1 2HD

<b>Present:</b>	1. Chair Jane Adam	Present for all notes
	2. Professor Iain Squire	Present for all notes
	3. Dr Alec Miners	Present for all notes
	4. Dr Ian Lewin	Present for all notes
	5. Dr Brain Shine	Present for all notes
	6. Dr Jeremy Braybrooke	Present for all notes
	7. Dr Peter Sims	Present for all notes
	8. Mr David Thomson	Present for all notes
	9. Mrs Pamela Rees	Present for all notes
	10. Dr Graham Ash	Present for all notes
	11. Professor Olivia Wu	Present for all notes
	12. Dr Andrew England	Present for all notes
	13. Professor Aileen Clarke	Present for all notes
	14. Dr John Watkins	Present for all notes
	15. Mr Stephen Sharp	Present for all notes
	16. Professor John McMurray	Present for all notes
	17. Mrs Sarah Parry	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	Technical Appraisal Administrator, National Institute for Health and Care Excellence	Present for all notes
Sophie Laurenson	Technical Analyst, National Institute for Health and Care Excellence	Present for all notes
Joanna Richardson	Technical Adviser, National Institute for Health and Clinical Excellence	Present for all notes

### **ERG**

Stephen Palmer	Professor of Health Economics, centre for Health Economics, University of York	Present for all notes
Marta Soares	Senior Research Fellow, Centre for Health Economics, University of York	Present for all notes
Mark Corbett	Research Fellow, Centre for Reviews and Dissemination, University of York	Present for all notes
Eleftherios Sideris	Research Fellow, Centre for Health Economics, University of York	Present for all notes

### **Clinical Experts**

Dr Karl Gaffney	Consultant Rheumatologist, nominated by British Society for	Present for all notes
Dr Raj Sengupta	Rheumatology Consultant Rheumatologist,	Present for all notes

nominated by British  
Society for  
Rheumatology

**Patient Experts**

Mrs Debbie Cook

Patient group, nominated  
by National Ankylosing  
Spondylitis Society

Present for all notes

Mr Roger Stevens

Patient group, nominated  
by National Ankylosing  
Spondylitis Society

Present for all notes

**Guideline  
Development group**

Dr Jon Packham

Consultant  
Rheumatologist  
nominated by NICE GDG

Present for all notes

Dr Louise Warburton

GPwSI

Present for all notes

**Non-public observers:**

Ria Skelton

NICE, Medical Editor

Melinda Kay

NICE, Corporate office

Lizzie Amis

NICE, Patient  
Involvement Programme

Gabriel Rogers

NICE, Technical Analyst

Steven Ward

NICE

Katherine McAllister

NICE

Deborah Morrison

NICE

## 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 TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of TA143 and TA233) [ID694].
2. The Chair informed the Committee of the non-public observers at this meeting: Lizzie Amis, Ria Skelton, Melinda Kay, Gabriel Rogers, Steven Ward, Katherine McAllister and Deborah Morrison
3. **Apologies were received from:** Dr Thanos Anastasiou, Dr Gerardine Bryant, Mr Adrian Griffin, Dr Anne McCune, and Ellen Rule

### Notes from the last meeting

4. The minutes from the previous meeting were agreed.

### Appraisal of TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of TA143 and TA233)

#### Part 1 – Open session

5. The Chair welcomed the invited experts: Mrs Debbie Cook, Mark Corbett, Dr Karl Gaffney, Dr Raj Sengupta, Dr Jon Packman, Dr Louise Warburton, Mr Roger Stevens, Mr Stephen Palmer, Eleftherios Sideris and Marta Soares to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from **Merck, Sharp and Dohme, Napp Pharmaceuticals, Pfizer and UCB** to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
  - 7.1. Dr Jane Adam, Dr Mohit Misra, Dr Alec Miners, Dr Ian Lewin, Dr Brian Shine, Dr Jeremy Braybrooke, Dr Peter Sims, Mr David Thomson, Mrs Pamela Rees, Dr Graham Ash, Professor Olivia Wu, Dr Andrew England, Professor Aileen Clarke, Dr John Watkins, Mr Stephen Sharp, Mrs Sarah Perry all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of TA143 and TA233)
  - 7.2. Dr Eldon Spackman declared a personal specific non-financial interest as he is employed by the Evidence Review Group (Centre for Health Economic, University of York and helped with the economic modelling.
    - 7.2.1. It was agreed that Dr Eldon Spackman could attend part 1 of the meeting, however he remained absent from the meeting.

- 7.3. Professor John McMurray declared a non personal, non-specific pecuniary interest as he has sat on a clinical trial steering committee in diabetic neuropathy for AbbVie. He has been on a Data Safety Monitoring Committee (DSMC) for a lipid lowering trial for Pfizer and he has sat on a MSD DSMC for a diabetes trial. It was confirmed that Glasgow University is paid for those activities.  
It was agreed that this declaration would not prevent Professor McMurray from participating in the meeting.
- 7.3.1. Mr Adrian Griffin declared a personal specific pecuniary interest as his employers Johnson and Johnson have rights to one of the comparator drugs for this appraisal.
- 7.3.2. It was agreed that this declaration would prevent Mr Adrian Griffin from participating in this section of the meeting and he remained absent from the meeting.
- 7.4. Dr Paul Robinson declared a personal specific pecuniary interest as he is employed by Merck Sharp & Dohme, the manufacturer of two of the products included in the appraisal.
- 9.5.1 It was agreed that this declaration would prevent Dr Paul Robinson from participating in this section of the meeting, but attended as a public observer for part 1 of the meeting.
8. The Chair asked all NICE Staff to declare any relevant interests.
- 8.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of TA143 and TA233).
9. The Chair asked the Guidance Development Group to declare any relevant interests.
- 9.1. Dr Jon Packman declared a non-personal, financial specific pecuniary interest as he has been involved in a number of pharmaceutical trials as PI and sub investigator as part of his role as a consultant rheumatologist. These involved numerous pharmaceutical companies with no 'preferred collaborator' status. He declared he was not currently acting as CI for any studies.
- 9.2. Dr Jon Packman also declared a personal, non-specific pecuniary interest as his wife is director of a training company for pharmaceutical companies. She regularly trains all top 20 companies in the UK (on aspects of medical information and ABPI code of practice), but has no specific links to any of these. Her accounts were reviewed by NICE during the process of his application to the SpA GDG in 2014 and no company specific conflicts were identified.

- 9.2.1. It was agreed that this declaration would not prevent Dr Jon Packman from participating in this section of the meeting
- 9.3. Dr Louise Warburton declared a non-personal specific pecuniary interest as she is a member of spondyloarthritis GDG and previously a member of a PSA group for AbbVie.
  - 9.3.1. It was agreed that this declaration would not prevent Dr Louise Warburton from participating in this section of the meeting
10. The Chair asked all other invited guests: AG and invited experts, to declare their relevant interests.
  - 10.1. Debbie Cook, Mark Corbett, Stephen Palmer, Marta Soares, Eleftherios Sideris and Roger Stevens all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of TA143 and TA233).
  - 10.2. Dr Karl Gaffney declared a personal non specific pecuniary interest as he has received research grants, sponsor and consultancy fees from Pfizer, AbbVie, MSD and UCB.
    - 10.2.1. It was agreed that this declaration would not prevent Dr Karl Gaffney from participating in this section of the meeting
  - 10.3. Dr Raj Sengupta declared a personal non-specific pecuniary interest as he has sat on advisory board and received speaker fee from AbbVie, MSD, Pfizer and UCB
    - 10.3.1. It was agreed that this declaration would not prevent Dr Raj Sengupta from participating in this section of the meeting
11. The Chair introduced the lead team, **Dr Mohit Misra, Mr David Thomson and Dr Alec Miners** who gave presentations on the clinical effectiveness and cost effectiveness of TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of technology appraisal 143 and technology appraisal 233).
12. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of technology appraisal 143 and technology appraisal 233) on the basis of the evidence before them, and potential equality issues raised in this appraisal.
13. They sought clarification and advice from the experts present. The discussions included:
  - 13.1. The diagnosis of ankylosing spondylitis and non-radiographic axial spondyloarthritis and the differentiation between the 2 conditions.

- 13.2. The current management of ankylosing spondylitis and non-radiographic axial spondyloarthritis and the experience of people treated with TNF-alpha inhibitors.
  - 13.3. Whether the clinical trials identified by the Assessment Group were generalisable to UK clinical practice.
  - 13.4. The results of the Assessment Group's meta-analysis, and whether TNF-alpha inhibitors should be considered separately or as a class.
  - 13.5. Whether the magnitude of response to TNF-alpha inhibitors was the same or different for the 2 conditions.
  - 13.6. How the companies and Assessment Group modelled the probability of initial response, the size of initial response for responders and non-responders, and the long-term effectiveness of TNF-alpha inhibitors.
  - 13.7. The cost effectiveness estimates of TNF-alpha inhibitors in both conditions, particularly any uncertainty around model assumptions and cost-effectiveness results.
  - 13.8. The clinical and cost-effectiveness evidence for treatment with a second or third TNF-alpha inhibitor for a person whose disease does not respond to treatment, or for someone who experiences a loss of response (sequential treatment).
- 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, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

- 17. The Committee continued to discuss the clinical and cost effectiveness TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of technology appraisal 143 and technology appraisal 233).
- 18. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

## **Date, time and venue of the next meeting**

- 19. Wednesday 25<sup>th</sup> March **at** the Royal College of General Practitioners, 30 Euston Square, London, NW1 2HD (EXTERNAL VENUE)