



# AWTTC

All Wales Therapeutics & Toxicology Centre  
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

## Interim Pathways Commissioning Group (IPCG)

**Draft minutes of the meeting held Monday 28<sup>th</sup> November 2016  
in the Boardroom, Llandough Hospital**

### **Members in attendance:**

Sharon Hopkins, Director of Public Health, C&V, IPCG Chair  
Alan Clatworthy, Clinical Effectiveness and Formulary Pharmacist, ABMU  
Ian Campbell, Hospital Consultant C & V, NMG representative  
Rick Greville, Director Wales ABPI Cymru Wales  
Geoff Greaves, CHC representative  
Sue Jeffs, Hospital Consultant AB, AWPAG representative  
Brian Hawkins, Chief Pharmacist, Medicines Management, Cwm Taf HB  
Jonathan Simms, Clinical Director of Pharmacy, AB  
Stuart Davies, Finance Director, WHSSC  
Andrew Champion, Assistant Director of Evidence, Evaluation and Effectiveness,  
IPFR representative WHSSC

### **Via teleconference:**

William Oliver, Assistant Director of Therapies and Health Science, HD  
Debra Fitzsimmons, Health Economist, Health Outcomes, WHESS  
Teena Grenier, Medicines Governance Lead, Betsi Cadwaladr HB  
Stuart Bourne, Deputy Director Public Health, Powys HB (by telephone)

### **AWTTC:**

Ruth Lang, Head of Liaison and Administration  
Tony Williams, Senior Appraisal Pharmacist, Team Manager  
Gail Woodland, Senior Appraisal Pharmacist  
Rosie Spears, Appraisal Scientist  
Jess Davis, Medical Writer

### **Clinical experts:**

Dr Michael Stone, Consultant Physician and Director of Bone Research, Cardiff  
University Academic Centre (Assessment 1 - Denosumab)

### **List of Abbreviations:**

AB	Aneurin Bevan
ABPI	Association of the British Pharmaceutical Industry
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics & Toxicology Centre
CHC	Community Health Council
C&V	Cardiff and Vale
ESR	Evidence Status Report
HB	Health Boards
HD	Hywel Dda
ICER	Incremental cost-effectiveness ratio
IPCG	Interim Pathways Commissioning Group
IPFR	Independent Patient Funding Request
NICE	National Institute for Health and Care Excellence



# AWTTC

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NMG  
WHESS  
WHSSC  
WMIC

New Medicines Group  
Welsh Health Economic Support Service  
Welsh Health Specialised Services Committee  
Welsh Medicines Information Centre

## 1. Welcome and Introduction

The Chair opened the meeting and welcomed members.

## 2. Apologies

Fiona Woods, Director, WMIC, C&V  
Jamie Duckers, Consultant, C&V Deputy  
Bethan Tranter, Chief Pharmacist, Velindre Trust  
Jason Lester, Deputy Clinical Director, Velindre Trust  
James Coulson, Clinical Pharmacologist, C&V  
Karen Samuels, Head of HTA, AWTTC

## 3. Minutes of previous meeting

The draft minutes of the previous meeting were checked for accuracy and confirmed. It was confirmed that the minutes would be made available on the AWTTC website.

## 4. Declaration of Interests / Confidentiality

The Chair reminded members that all IPCG proceedings are confidential and should not be disclosed outside of the meeting. Members were asked to ensure they had signed and returned the confidentiality statements to AWTTC. The Chair invited any declarations of interest – there were none.

## 5. Assessment 1 - (Deferred from IPCG meeting 26Sep16)

**Denosumab (Prolia<sup>®</sup>)** for the treatment of osteoporosis in men at increased risk of fractures.

The Chair briefly outlined the sequence of events and set the context of the meeting.

The Chair invited any declarations of interest specific to this assessment; there were none.

Rosie Spears presented the key aspects of the evidence status report (ESR).

The Chair introduced the clinical expert, Dr Michael Stone. The Chair described the role of the clinical experts as invited observers of the IPCG meeting to answer questions and input into discussions to enable members to gain a better clinical understanding of the clinical context. The Chair highlighted that clinical experts were nominated by their specialist group or network and should not express personal opinion or promote the use of a medicine. The Chair confirmed that Dr Stone would leave the meeting after the assessment and prior to the vote.

The Chair opened general discussion in relation to clinical effectiveness. Dr Stone confirmed that AWTTC had accurately represented the evidence in the assessment report. He stated that the number of patients estimated by the marketing authorisation holder had been higher than he would have predicted and, in his view,



the reasons for this had been accurately documented in the assessment report. Dr Stone said that clinical effectiveness in men is comparable with women. It was noted that NICE are currently updating their guidelines. Clarification was sought on the place in therapy and it was confirmed that denosumab would be used third line after failure of two oral bisphosphonates in patients unsuitable for zoledronic acid or fourth line after failure of zoledronic acid or the development of severe renal impairment during treatment.

Members considered the budget impact estimates. Members sought assurances from Dr Stone that he was confident in the number of eligible patients estimated. Dr Stone said that he was confident in the estimates and explained that clinicians take a number of issues into account before committing patients to long-term treatment.

The Chair invited general discussion of any cost effectiveness issues. It was acknowledged that the medicine acquisition costs used in the Swedish cost effectiveness model would be different to those in Wales. It was noted that the company declined to provide a commercial arrangement and Gail Woodland highlighted that there is no requirement for the company to provide cost-effectiveness data to NICE in relation to a multiple-technology appraisal.

The Chair invited members to discuss the patient/public perspective. The associated decrease in quality of life and increase in mortality, following a fracture was highlighted. There was discussion in relation to gender equality and the access criteria applied to women across health boards in Wales. It was noted that if recommended by IPCG, the NICE criteria for denosumab treatment in women should be applied to men, to ensure equity of access to male and female patients. Differences in approach and interpretation of the NICE appraisal guidelines in relation to women were acknowledged. Clarification was sought in relation to the collection of clinical outcome information and Dr Stone confirmed that this would be undertaken via the specialist network.

The IPCG recommendation for Health Boards Chief Executives was agreed:

### **Denosumab (Prolia®) for the treatment of osteoporosis in men at increased risk of fractures**

Using the agreed criteria, denosumab (Prolia®) can be made available within NHS Wales for the treatment of osteoporosis in men at increased risk of fractures.

### **6. Date of next meeting**

The Chair confirmed the next meeting would be held on Monday 23<sup>rd</sup> January 2017 in Cardiff.

The Chair then thanked members for their participation and closed proceedings.