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

Interim Pathways Commissioning Group (IPCG)

Draft minutes of the meeting held Monday 26th September 2016 in the MDT Seminar Room, Llandough Hospital

Members in attendance:
Sharon Hopkins, Director of Public Health, C&V, IPCG Chair
Alan Clatworthy, Clinical Effectiveness and Formulary Pharmacist, ABMU
William Oliver, Assistant Director of Therapies and Health Science, HD
Joe Ferris, Outcomes Manager, Wales ABPI Cymru Wales
Geoff Greaves, CHC representative
Sue Jeffs, Hospital Consultant AB, AWPAG representative
Simon Waters, Consultant Oncologist, Velindre Trust
Debra Fitzsimmons, Health Economist, Health Outcomes, WHESS (by telephone)
Brian Hawkins, Chief Pharmacist, Medicines Management, Cwm Taf HB
Stuart Bourne, Deputy Director Public Health, Powys HB (by telephone)
Teena Grenier, Medicines Governance Lead, Betsi Cadwaladr HB (via VC)

AWTTC:
Ruth Lang, Head of Liaison and Administration
Karen Samuels, Head of Patient Access to Medicines Service
Gail Woodland, Senior Appraisal Pharmacist
Jess Davis, Medical Writer

Clinical experts:
Debbie Stone, Service Development Manager and Specialist nurse, National Osteoporosis Society (Assessment 1 - Denosumab)
Dr Steven Knapper, Consultant Haematologist, University Hospital of Wales (Assessment 2 – Arsenic trioxide)

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
NMG	New Medicines Group
WHESS	Welsh Health Economic Support Service
WHSSC	Welsh Health Specialised Services Committee
WMIC	Welsh Medicines Information Centre

1. Welcome and Introduction
The Chair opened the meeting and welcomed members.

2. Apologies

Fiona Woods, Director, WMIC, C&V
Bethan Tranter, Chief Pharmacist, Velindre Trust
Ian Campbell, Hospital Consultant C & V, NMG representative
James Coulson, Clinical Pharmacologist, C&V
Jamie Duckers, Consultant, C&V Deputy
Rick Greville, Director Wales ABPI Cymru Wales (Joe Ferris deputising)
Jonathan Simms, Clinical Director of Pharmacy, AB
Stuart Davies, Finance Director, WHSSC
Andrew Champion, Assistant Director of Evidence, Evaluation and Effectiveness, IPFR representative WHSSC

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
Denosumab (Prolia®) 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.

Gail Woodland presented the key aspects of the evidence status report (ESR).

The Chair introduced the clinical expert, Debbie 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 Mrs Stone would leave the meeting after the first assessment and prior to the vote.

The Chair opened general discussion in relation to clinical effectiveness. The discrepancy in the number of patients estimated by the marketing authorisation holder compared to clinical experts was highlighted and discussed. It was noted that the company estimates of the number of eligible patients were considerably higher.

Mrs Stone confirmed that Professor O'Neill would be providing a clinical expert report. Members were informed that it had only been received by AWTTC this morning and unfortunately members had not had sight of it prior to the meeting.

Mrs Stone stated that a clear and methodical shared care agreement would need to be in place prior to prescribing. In addition, a register of patients would need to be available and date of review for each patient would need to be agreed. A plan for the management of any side effects would also be required.

Members considered the budget impact estimates. It was confirmed that the potential cost of treating fractures and other societal costs had not been included in the estimate. It was highlighted that the marketing authorisation holder had not engaged in the AWMSG appraisal process and provided a submission within the required timescale. A statement of advice not supporting use within NHS Wales had been published by AWMSG following endorsement by Welsh Government. Mrs Woodland confirmed that the company are now pursuing health technology appraisal with NICE. There was discussion over the acquisition costs. It was confirmed that the marketing authorisation holder had declined to submit a commercial access arrangement.

The Chair invited general discussion of any cost effectiveness issues. Members discussed the available evidence and agreed that it was subject to significant uncertainty and assumptions. Mr Clatworthy made the point that there is more comparability with the Canadian model rather than the Swedish model which included postmenopausal women, as the former had undertaken an indirect comparison in men which he considered to be more appropriate. Mrs Samuels confirmed that it is not within the remit of AWTTC to undertake cost-effectiveness modelling.

The Chair invited members to discuss the patient/public perspective. The gap in information regarding the inclusion of wider societal issues within the case for cost-effectiveness and lack of clarity regarding patient numbers was noted. Mrs Stone confirmed that strontium ranelate was not regularly prescribed and teriparatide would be used for a different sub-set of patients.

Following discussion the Chair suggested that the available evidence was insufficient and clarification of the outstanding issues would be required in order for IPCG to make a recommendation to the Chief Executive Team. There was unanimous agreement to defer the assessment pending additional information and clarification of the outstanding issues.

6. Assessment 2

Arsenic trioxide (TRISENOX®) in combination with all-trans retinoic acid for the first-line treatment of acute promyelocytic leukaemia in adult patients unsuitable for anthracycline-based therapy

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

Gail Woodland provided an overview of the key aspects of the ESR.

The Chair introduced the clinical expert, Dr Steven Knapper. 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 Knapper would leave the meeting after the first assessment and prior to the vote.

The Chair opened general discussion in relation to clinical effectiveness and invited the clinical expert to respond. Dr Knapper stated that he was impressed with the summary and set the clinical context. He explained that the condition is rare and anticipated there would only be around five eligible patients in Wales per year. He confirmed that this medicine could be delivered as a day case and would offer a potentially curative treatment for elderly and frail people. He explained that liver toxicity could sometimes be an issue and patients' fitness for treatment would be assessed prior to commencing treatment. He explained that patients in Wales have been receiving the treatment via successful IPFR applications and have been monitored with long-term follow up.

The Chair invited general discussion of any cost effectiveness issues and members considered the appropriateness of the evidence. It was confirmed that the marketing authorisation holder had not provided a commercial arrangement.

The Chair invited members to discuss the patient/public perspective. The clinical expert explained that there would be a group of elderly patients too frail for anthracycline treatment and a group of patients under 65 who would not be considered fit enough for such treatment.

The Chair invited members to discuss any wider issues. It was confirmed that the marketing authorisation holder is progressing a licence. Mrs Lang highlighted that early appraisal by AWMSG would always be the preferred route for a licensed medicine. There was agreement that an interim commissioning decision by IPCG regardless of the licensing issue should be pursued because of the high unmet clinical need as the licence would not include all patients in this group.

The Chair thanked Dr Knapper for his valuable contribution to the discussion and he left the meeting. The vote was taken.

The IPCG recommendation for Health Boards Chief Executives was agreed:

Arsenic trioxide (TRISENOX®) in combination with all-trans retinoic acid for the first-line treatment of acute promyelocytic leukaemia in adult patients unsuitable for anthracycline-based therapy.
Arsenic trioxide (TRISENOX®) can be made available within NHS Wales to be used in combination with all-trans retinoic acid for the first line treatment of acute promyelocytic leukaemia, characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha gene, in adult patients unsuitable for anthracycline-based therapy.

7. Date of next meeting

The Chair confirmed the next meeting would be held on Monday 28th November 2016 in Cardiff.

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