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

Interim Pathways Commissioning Group (IPCG)

Minutes of the meeting held Tuesday 29th August 2017 in the Academic Centre, University Hospital Llandough, Cardiff CF64 2XX

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 of ABPI Wales
Geoff Greaves, CHC representative
Fiona Woods, Director, WMIC, C&V
Stuart Davies, Finance Director, WHSSC
Bethan Tranter, Chief Pharmacist, Velindre Trust
James Coulson, Clinical Pharmacologist, C&V

Via teleconference:
Debra Fitzsimmons, Health Economist, Health Outcomes, WHESS
Stuart Bourne, Deputy Director Public Health, Powys

Via video conference:
Teena Grenier, Medicines Governance Lead, Betsi Cadwaladr
Will Oliver, Assistant Director of Therapies and Health Science, Hywel Dda

AWTTC:
Phil Routledge, Clinical Director
Tony Williams, Senior Appraisal Pharmacist, Team Manager
Gail Woodland, Senior Appraisal Pharmacist
Rosie Spears, Appraisal Scientist
Jessica Davis, Medical Writer
Laura Phillips, Administration Assistant

List of Abbreviations:

ABMU	Abertawe Bro Morgannwg University
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
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

Sue Jeffs, Hospital Consultant AB, AWPAG representative
Jonathan Simms, Clinical Director of Pharmacy, Aneurin Bevan
Andrew Champion, Assistant Director of Evidence, Evaluation and Effectiveness, IPFR representative WHSSC
Brian Hawkins, Chief Pharmacist, Cwm Taf
Kamal Asaad, Medical Director, Cwm Taf
Sian Lewis, Deputy Medical Director, WHSSC
Ruth Lang, Head of Liaison and Administration, AWTTC

3. Minutes of previous meeting

The draft minutes of the previous meeting were checked for accuracy and approved. 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

Axitinib (Inlyta®▼) for the treatment of advanced renal cell carcinoma after failure of prior treatment with pazopanib.

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 review document.

The Chair opened general discussion on the review. Members considered the availability of newly licensed alternative medicines and NICE technology appraisal advice. The assessment lead highlighted that axitinib is included in European Society for Medical Oncology (ESMO) guidelines, published in September 2016. Members questioned whether off-label axitinib continues to fit the criteria for a One Wales decision due to the availability of licensed alternative medicines. It was noted that clinical expert clarification is needed to confirm whether there are a group of patients who cannot tolerate the licensed alternative medicines and therefore suitable for off-label axitinib treatment. One member added that there is still a clinical need for axitinib as patients in their health board have recently started treatment. It was highlighted that axitinib is currently included in the NICE clinical pathway. One member commented that axitinib is being used further down the treatment pathway i.e. third and fourth line. It was confirmed that this is supported by clinical expert opinion.

Following discussion, the Chair suggested that the relevant information was not available and clarification of the outstanding issues would be required in order for IPCG to make a recommendation to the health board Chief Executives. There was agreement to defer the review pending additional information and clarification of the outstanding issues.

6. Assessment 2

Bevacizumab (Avastin®) at a dose of 7.5 mg/kg in combination with carboplatin and paclitaxel for the front-line treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer.

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

Gail Woodland presented the key aspects of the review document.

The Chair opened general discussion on the review. The recently published cost-effectiveness data were highlighted and discussed. The health economist described the analysis as robust. Members noted that the cost per quality-adjusted life-year (QALY) was above the conventional £20,000–£30,000 threshold. The plausibility of vial sharing was questioned. The assessment lead highlighted that this is a life limiting disease and questioned whether the conventional cost-effectiveness threshold should be considered.

Members sought clarification on the high risk patient group. The assessment lead confirmed that patients with high risk disease are those with FIGO stage III debulked but residual disease more than 1.0 cm or stage IV disease, or stage III disease at presentation and requiring neoadjuvant chemotherapy due to low likelihood of optimal primary surgical cytoreduction.

Members asked whether there are any licensed alternative medicines for the indication under consideration. The assessment lead confirmed that there are no licensed alternative medicines available.

Members were very grateful of the patient outcome data provided by South East Wales Cancer Centre. It was noted that the progression free survival and the adverse drug events reported are consistent with those reported in the clinical trial.

Following discussion, there was agreement that the new evidence warrants a reassessment of the One Wales decision. AWTTC will produce a new Evidence Status Report which will be discussed and considered at a future IPCG meeting.

7. Assessment 3

Docetaxel in combination with androgen deprivation therapy for the treatment of hormone-naïve metastatic prostate cancer.

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

Gail Woodland presented the key aspects of the review document.

The Chair opened general discussion on the review. The technology appraisal in process with NICE for abiraterone was highlighted and discussed. Members asked whether abiraterone has received a licence. The assessment lead confirmed that abiraterone has not yet received a licence.

Members discussed which outcomes could be meaningfully measured across Wales. It was suggested that the time to progression would be the preferred data to collect. It was also suggested that tolerability data should be collected since some individual

patient funding requests had been submitted for abiraterone for patients who do not tolerate docetaxel.

Proceedings were concluded by the Chair and members asked to vote. The IPCG recommendation for Health Boards Chief Executives was agreed:

Docetaxel in combination with androgen deprivation therapy for the treatment of hormone-naive metastatic prostate cancer

Date of original IPCG recommendation: Friday 27th May 2016
Date of review: Tuesday 29th August 2017

Using the agreed starting and stopping criteria, docetaxel, in combination with androgen deprivation therapy, can continue to be made available within NHS Wales for the treatment of men with hormone-naive metastatic prostate cancer

Docetaxel is not licensed to treat this indication and is therefore 'off-label'. Each provider organisation must ensure all internal governance arrangements are completed before this medicine is prescribed.

The risks and benefits of the off-label use of docetaxel for this indication should be clearly stated and discussed with the patient to allow informed consent.

Providers should consult the General Medical Council Guidelines on prescribing unlicensed medicines before any off-label medicines are prescribed.

This advice will be reviewed after 12 months or earlier if new evidence becomes available.

8. Date of next meeting
The Chair confirmed the next meeting would be held on Monday 25th September 2017 in Cardiff.

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