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

Interim Pathways Commissioning Group (IPCG)

Minutes of the meeting held Monday 26th June 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 Wales ABPI Cymru Wales
Geoff Greaves, CHC representative
Fiona Woods, Director, WMIC, C&V
Brian Hawkins, Chief Pharmacist, Medicines Management, Cwm Taf HB
Jonathan Simms, Clinical Director of Pharmacy, AB
Andrew Champion, Assistant Director of Evidence, Evaluation and Effectiveness, IPFR representative WHSSC

Via teleconference:
Jo Charles, Research Fellow, CHEME, Bangor University
Will Oliver, Assistant Director of Therapies and Health Science, HD

Via video conference:
Teena Grenier, Medicines Governance Lead, Betsi Cadwaladr HB

AWTTC:
Phil Routledge, Clinical Director
Karen Samuels, Head of HTA, AWTTC
Gail Woodland, Senior Appraisal Pharmacist
Rosie Spears, Appraisal Scientist
Jessica Davis, Medical Writer
Laura Phillips, Administration Assistant

Clinical experts:
Professor Alex Anstey, Consultant Dermatologist, Betsi Cadwaladr HB

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
CHEME	Centre for Health Economics and Medicines Evaluation
CHC	Community Health Council
C&V	Cardiff and Vale
ESR	Evidence Status Report
HB	Health Boards
HD	Hywel Dda
IPCG	Interim Pathways Commissioning Group
IPFR	Independent Patient Funding Request

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
James Coulson, Clinical Pharmacologist, C&V
Stuart Davies, Finance Director, WHSSC
Stuart Bourne, Deputy Director Public Health, Powys
Bethan Tranter, Chief Pharmacist, Velindre Trust
Deborah Fitzsimmons, Health Economist, Health Outcomes, WHESS

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
Rituximab for the treatment of pemphigus and pemphigoid disease in adults and children where third- or fourth-line treatments, including steroids and steroid-sparing treatments have failed.

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, Prof Alex Anstey. 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 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 opened general discussion in relation to clinical effectiveness. Prof Anstey confirmed that AWTTC had accurately represented the evidence in the ESR. He noted that pemphigoid is more common in older patients and usually managed by topical steroids in the community and rituximab is very rarely used. Rituximab is more

frequently used for the treatment of pemphigus. Pemphigus is very difficult to treat, more common in younger patients and the exposure of ruptured skin increases the risk of sepsis. He highlighted that pemphigus and pemphigoid are very rare diseases.

Members sought clarification on the dose of rituximab for the treatment of pemphigus and pemphigoid. The assessment lead confirmed that the rituximab dose was 1 g on days 1 and 15. This is the dose used for the treatment of rheumatoid arthritis and the dose recommended by the NHS England Clinical Commissioning Policy for the third-line treatment of pemphigus and fourth-line treatment of pemphigoid disease. Prof Anstey highlighted that in the Wang et al. meta-analysis which examined the efficacy of different dosing regimens of rituximab, the high-dose group, which included the rheumatoid arthritis dose, was the most clinically effective. Members noted that the rheumatoid arthritis dose of rituximab was being requested through IPFR.

Members considered the place in the treatment pathway for the comparator intravenous human normal immunoglobulin (IVIG) and its availability in NHS Wales. It was agreed that IVIG would be used after rituximab treatment and access to this medicine would be via IPFR. Members noted the high complete remission rates achieved with rituximab and consequently if recommended the number of IPFRs for IVIG would likely be low. Prof Anstey added that the majority of patients do not require rituximab treatment and of those that do, the number of patients who relapse is very low. The Chair highlighted the importance of the collection of outcome data to capture these events.

Members discussed the availability of rituximab biosimilars. Prof Anstey highlighted that it is important to recognise that biosimilars are similar medicines and are not the same. He stated that studies investigating the clinical efficacy and safety of biosimilars exist in more common diseases and it may be reasonable to extrapolate the data from these studies.

The Chair invited general discussion of any cost effectiveness issues. Members noted that no cost effectiveness data from the UK were available. No patient access scheme (PAS) was offered by the company because rituximab is off-label for this indication.

Members considered the budget impact estimates. The assessment lead commented that clinical experts had indicated that the patient numbers included in the budget impact estimates may be slightly high for year one but the population being treated is likely to grow over time. Additionally, it was noted that about half of these patients will be already accessing this medicine through IPFR. Members highlighted that these patients are commonly treated in intensive care or a high dependency unit and the nursing costs associated are substantial. These costs were not included in the budget impact estimates. The assessment lead commented that care costs would be included in a health economic model and not part of the budget impact.

The Chair invited members to discuss the patient/public perspective. No additional patient/public perspective issues were raised.

The clinical expert left the meeting and members were invited to vote. The IPCG recommendation for Health Boards Chief Executives was agreed:

Rituximab for the treatment of pemphigus and pemphigoid disease in adults and children where third- or fourth-line treatments, including steroids and steroid-sparing treatments have failed

Date of advice: Monday 26th June 2017

Rituximab can be made available within NHS Wales for the third-line treatment of pemphigus and fourth-line treatment of pemphigoid disease in adults and children whose disease has not responded to previous treatments including steroids and steroid-sparing agents.

Rituximab is not a 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 rituximab 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.

6. Date of next meeting

The Chair confirmed the next meeting would be held on Monday 24th July 2017 in Cardiff.

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