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

Interim Pathways Commissioning Group (IPCG)

Minutes of the meeting held Monday 22nd August 2016 in the Llandough Hospital Boardroom

Members in attendance:
Sharon Hopkins, Director of Public Health, C&V, IPCG Chair
Fiona Woods, Director, WMIC, C&V
Jonathan Simms, Clinical Director of Pharmacy, AB
Alan Clatworthy, Clinical Effectiveness and Formulary Pharmacist, ABMU
William Oliver, Assistant Director of Therapies and Health Science, HD
Andrew Champion, Assistant Director of Evidence, Evaluation and Effectiveness, IPFR representative WHSSC
Bethan Tranter, Chief Pharmacist, Velindre Trust
Ian Campbell, NMG Hospital Consultant representative
James Coulson, Clinical Pharmacologist, C&V
Stuart Davies Finance Director, WHSSC
Rick Greville, Director Wales ABPI Cymru Wales
Geoff Greaves, CHC representative
Sue Jeffs, Consultant Anaesthetist, AWPAG representative
Debra Fitzsimmons, Health Economist, Health Outcomes, WHESS (by telephone)

AWTTC:
Anthony Williams, Senior Appraisal Pharmacist Team Leader
Ruth Lang, Head of Liaison and Administration
Gail Woodland, Senior Appraisal Pharmacist
Rosie Spears, Senior Appraisal Scientist
Jess Davis, Medical Writer

Observers:
Ann-Marie Matthews, IPFR Manager/Lead for Value based Healthcare, AB

Clinical expert:
Dr Richard Lee, Lead for Experimental Medicine in Ocular Inflammatory Diseases, University Hospitals Bristol and Moorfields NHS Foundation Trusts and University of Bristol

List of Abbreviations:

AB	Aneurin Bevan
ABPI	Association of the British Pharmaceutical Industry
ADT	Androgen deprivation therapy
ASAR	AWMSG Secretariat Assessment Report
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics & Toxicology Centre
BCU	Betsi Cadwaladr University
CHC	Community Health Council
CT	Cwm Taf
C&V	Cardiff and Vale
ESR	Evidence Status Report

GCSF	Granulocyte colony stimulating factor
HB	Health Boards
HD	Hywel Dda
ICER	Incremental cost-effectiveness ratio
IPCG	Interim Pathways Commissioning Group
IPFR	Independent Patient Funding Request
NMG	New Medicines Group
NICE	National Institute for Health and Care Excellence
OS	Overall survival
P	Powys
RCC	Renal cell carcinoma
SMC	Scottish Medicines Consortium
VCC	Velindre Cancer Centre
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
Brian Hawkins, Chief Pharmacist, medicines management, Cwm Taf HB
Stuart Bourne, Deputy Director Public Health, Powys HB
Teena Grenier, Medicines Governance Lead, Betsi Cadwaladr HB

3. 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.

4. Assessment 1
Adalimumab (Humira®) for the treatment of paediatric patients with severe refractory uveitis.

The Chair briefly outlined the sequence of events and set the context of the meeting. The Chair confirmed that no additional new information should be presented to this group, other than that previously circulated to members.

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

Rosie Spears presented the key aspects of the evidence status report.

The Chair introduced the clinical expert, Richard Lee. The Chair described the role of the clinical expert as an invited observer 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 Lee would leave the meeting after the second assessment and prior to the vote.

The Chair opened general discussion in relation to clinical effectiveness. The rarity of the condition was highlighted. The clinical expert confirmed that members had been provided with a fair summary of the limited evidence available. He confirmed that use of a medicine outside of its licence was typical for this orphan disease and no epidemiological evidence is available. Dr Lee confirmed that adalimumab was internationally considered standard treatment. It was highlighted that the trial evidence provided related to the JIA indication and the clinical expert confirmed that it would not be feasible to undertake clinical studies in the non-JIA uveitis population due to low numbers. It was confirmed that 5-7 patients had been commissioned by WHSSC. It was noted that most IPFRs had been approved.

The Chair invited general discussion of any cost effectiveness issues. Debra Fitzsimmons reiterated the issues highlighted in the ESR and explained that the case for cost-effectiveness was very difficult to unravel due to the number of assumptions in relation to the clinical and quality of life evidence. The Chair referred to the budget impact and members discussed the duration of treatment. Mrs Woodland confirmed that the budget impact estimates in the ESR had been based on treatment duration of 24 months. Members acknowledged that if treatment increased to weekly from fortnightly then this would increase the budget impact. The monitoring costs were clarified. Mrs Woodland confirmed that the budget impact estimates were based on the BNF tariff. Reference was made to the availability of a rebate scheme and it was acknowledged that this would reduce the budget impact estimates significantly.

The Chair invited members to discuss the patient/public perspective. Members sought clarification from the clinical expert in relation to the risk of blindness when giving the treatment to children. He commented that long-term outcomes are difficult to collect. Members considered the impact on patients in receiving treatment in a specialist centre outside of Wales. The clinical expert explained what other treatment options were available. It was noted that the English commissioning advice was interim to the publication of the Sycamore trial.

The Chair thanked the clinical expert for his input and asked members to take a short break before moving on to the next assessment.

5. Assessment 2

Adalimumab (Humira®) for the treatment of adult patients with severe refractory uveitis

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 opened general discussion in relation to clinical effectiveness. Members were informed that data from the VISUAL trial had been not been released to the commissioners in NHS England and commissioning is not in place. Dr Lee confirmed that publication of VISUAL is expected within the next couple of months in

the Lancet. He commented that it was clear in terms of benefits to patients. Members noted that NICE advice was expected to be published in July 2017 and a One Wales decision would be interim to this. Representatives from AWTTC clarified that One Wales decisions would be reviewed by IPCG if significant new information became available that might impact on a One Wales decision. The Chair reminded members of the context of One Wales decisions. Members acknowledged that the evidence provided was limited. The clinical expert clarified the treatment options and explained why Osidex is not comparable in terms of clinical use.

The Chair invited general discussion of any cost effectiveness issues. The clinical expert explained that patients would normally be referred to specialist centres as local ophthalmology centres would not have the facilities to treat patients with this rare condition. It was confirmed that initiation of treatment would be specialist only. Members discussed the option of de-centralization. Dr Lee explained that blood tests would normally be done locally and the results passed back to the specialist nurse at the Centre. The Chair invited discussion of any budget impact issues. Members discussed the duration of treatment and fortnightly dosing regimen. It was noted that biosimilars on the horizon would be available at a much lower cost. It was confirmed that NICE advice for this indication would be available in July 2017 and reference was made to the commissioning decision in NHS England.

The Chair invited members to discuss the patient/public perspective. It was noted that the patient lobby had been very strong when NHS England had published negative advice. The lay member highlighted the cost of travel to specialist centres. Members sought clarification from the clinical expert in relation to the starting and stopping criteria in England.

The Chair invited members to discuss any wider issues. Dr Lee made the point that maintenance of access to this treatment is crucial and a One Wales decision should not cause a delay in the initiation of treatment for patients.

The Chair thanked Dr Lee for his valuable contribution to the discussion and asked him to leave the meeting prior to the vote.

The Chair asked members to vote on the paediatric indication first. This was followed by the vote for the adult indication.

The IPCG recommendations for Health Boards Chief Executives were agreed:

Adalimumab (Humira®) for the treatment of paediatric patients with severe refractory uveitis.
Using the agreed starting and stopping criteria, adalimumab (Humira®) can be made available within NHS Wales to treat paediatric patients (aged ≥ 2 to ≤ 18 years) with severe refractory non-infectious uveitis. Adalimumab (Humira®) should be initiated in specialist centres for this indication.

Adalimumab (Humira®) for the treatment of adult patients with severe refractory uveitis
Using the agreed starting and stopping criteria, adalimumab (Humira®) can be made available within NHS Wales to treat adult patients with severe refractory

non-infectious uveitis. Adalimumab (Humira®) should be initiated in specialist centres for this indication.

6. Date of next meeting

The Chair confirmed that the next meeting would be held on Monday 26th September 2016 in Cardiff and announced the medicines to be assessed:

- Arsenic trioxide for the first-line treatment of acute promyelocytic leukaemia (APL) in those patients deemed unsuitable for anthracycline-based chemotherapy (off-label)

- Denosumab for the treatment of osteoporosis in men

The Chair thanked members for their participation and closed proceedings.