



# AWTTC

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

## **One Wales Medicines Assessment Group (OWMAG)**

### **Minutes of the Teams meeting held Monday, 3<sup>rd</sup> June 2024**

#### Members in attendance

John Watkins, Consultant in Public Health, OWMAG Chair

Joe Castle, Operations Manager, ABPI Cymru Wales

Lindsay Davies, Senior Information Pharmacist, representative Cardiff and Vale

Stuart Wyn Evans, Clinical Effectiveness Pharmacist, representative Swansea Bay

Laurence Gray, Clinical Pharmacologist alternate representative

Will Hardy, Research Fellow, Bangor University, Health Economist

Kathryn Howard, Head of Pharmacy, Royal Glamorgan Hospital, representative Cwm Taf Morgannwg

William King, Consultant in Public Health, representative Powys

Michael Thomas, Consultant in Public Health Medicine, representative Hywel Dda

Simon Waters, Consultant Oncologist, alternate representative Velindre

#### **AWTTC**

Andrew Champion, Programme Director

Rachel Jonas, Medical Writer

Sara Pickett, Senior Health Economist

Rosie Spears, Senior Appraisal Scientist

Laura Taylor, Admin Supervisor

Tom Winfield, Senior Health Economist

Gail Woodland, Senior Appraisal Pharmacist

#### **Patient organisation representative**

Helen West, Guts UK

#### **List of Abbreviations:**

ABPI	Association of the British Pharmaceutical Industry
AWTTC	All Wales Therapeutics and Toxicology Centre
ESR	Evidence Status Report
IPFR	Individual Patient Funding Request
JCC	NHS Wales Joint Commissioning Committee
NICE	National Institute for Health and Care Excellence
NMG	New Medicines Group
OWMAG	One Wales Medicines Assessment Group



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## 1. Welcome and Introduction

The Chair opened the meeting and welcomed members.

## 2. Apologies

Tim Banner, Clinical Director Pharmacy & Medicines Management, representative Cardiff and Vale

Anthony Cadogan, Deputy Chief Pharmacist, representative Velindre

James Coulson, Clinical Pharmacologist representative

Malcolm Latham, Community Health Council, Lay representative

Eilir Hughes, Assistant Medical Director, representative Betsi Cadwaladr

Leo Pinto, Consultant in Public Health, representative Aneurin Bevan

Julie Wilson-Thomas, Community Health Council, alternate Lay representative

## 3. Welcome

The Chair opened the meeting and welcomed members. New members were introduced to replace previous members who have finished their eight-year memberships.

Tom Winfield, Senior Health Economist gave new members a presentation on Health Economics and the relevance to decision-making.

## 4. Declarations of Interests/Confidentiality

The Chair reminded members that all OWMAG proceedings are confidential and should not be disclosed outside of the meeting. Members were reminded that declarations of interest and confidentiality statements are signed by each member on an annual basis. The Chair invited any declarations of interest; there were none.

## 5. Assessment

### **Nivolumab for the treatment of dMMR/MSI-H gastro-oesophageal cancer.**

The Chair informed members there are no clinical experts or lay members attending this time due to non-availability. Helen West from Guts UK is attending as a patient organisation representative.

Rosie Spears presented an overview of the key aspects of the nivolumab evidence status report (ESR). Clarity was provided to members as to the reasons for the reassessment and what updates had been made to the ESR.

Patient numbers were discussed. It was highlighted that patient numbers in previous One Wales recommendations are not always reached and are often lower. Uncertainty is inevitable and projected numbers may differ due to variance in clinical presentation and initial uptake. Members were reminded decisions are reviewed at



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12 months review and OWMAG members can decide how frequent further reviews will be made to monitor patient outcomes and assist in data collection in Wales.

The original NICE covid guideline was discussed for this specific cohort and the rationale for choosing nivolumab as a monotherapy. Duration of treatment of both nivolumab and pembrolizumab were questioned and potential comparative safety data. There were no anticipated clinical trials in the pipeline for this patient cohort. It was noted that pembrolizumab has been approved for dMMR/MSI-H tumours (as later-line use). Clinical experts have submitted a request for nivolumab due to prior experience of use. There was also evidence presented that this particular mutation does not respond as well to chemotherapy. A broad literature search was performed by AWTTC for dMMR/MSI-H in first line setting to provide as much evidence to members as possible and pembrolizumab has a very similar mode of action so was felt to be appropriate. Members considered that there was reasonable evidence to indicate that pembrolizumab was a suitable proxy for nivolumab. Members considered that there may be opportunity to explore pembrolizumab in this setting as a future treatment option.

Tom Winfield presented an overview of the cost effectiveness section of the ESR. The Chair invited Will Hardy, OWMAG health economist to comment. A discrepancy was highlighted between the ESR and the presentation, correct figures were confirmed. Adherence of 100% is assumed and this may not be reflective of real world. It was noted however that treatment duration was based on the data from the pembrolizumab study compared to chemotherapy of 11.2 months and this was within the duration of the real-world data provided. Demographics used in the cost effectiveness section were considered to be reasonably reflective of the Welsh population. A discussion ensued as to whether there is the possibility to attain the QALY gains required to meet the cost effectiveness threshold and which threshold was most appropriate based on the evidence base presented and any associated uncertainties.

Rosie Spears presented budget impact section of the ESR. The Chair invited members to comment. Although not taken into account in the budget impact, the side effects of nivolumab can have significant costs which may be more than the costs of chemotherapy side effects. The projected patient numbers for immunotherapy-induced colitis from a One Wales review were given and confirmed likely small.

Rosie concluded the presentation to members with the patient impact and experience and additional considerations.

The Chair introduced the patient organisation representative Helen West from Guts UK. The Chair described the role of the patient organisation representative to attend meetings and observe proceedings, answer questions and input into discussion to give a better understanding from a patient and carer perspective. The Chair invited any declarations of interest from the patient organisation representative; there were



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none. Helen echoed the findings included in the presentation provided by Rosie around patient impact and experiences. Helen explained that the organisation is a go to group for this type of cancer. She noted this is a less survivable cancer, that patients and carers have concerns over treatment choices for oesophageal cancer. Side effects are a concern with chemotherapy and even if their (the patient's) survival is short, less side effects and some potential gain in survival would be beneficial to the patient and their carers. Rates of this type of cancer are increasing and a younger population is starting to emerge. The Chair thanked Helen for her comments.

The Chair opened the vote to members.

**Date of advice: Monday 03 June 2024**

It is the view of the One Wales Medicines Assessment Group (OWMAG) that nivolumab should not be supported within NHS Wales for monotherapy as a first-line treatment for patients with metastatic or locally advanced and unresectable, deficient mismatch repair (dMMR) / high microsatellite instability (MSI H) oesophageal and gastric cancer.

Individual Patient Funding Request (IPFR) consideration remains appropriate for those patients who are likely to obtain significantly more clinical benefit from the intervention than would normally be expected at a reasonable value for money.

The OWIR and OWID will be disseminated via email for members to comment.

The Chair thanked the group and closed the meeting at 12.37pm