

An Update to Accessing Medicines in Wales



Tony Williams

Senior Appraisal

Pharmacist, AWTTTC



AWTTTC

All Wales Therapeutics
& Toxicology Centre

Overview

- Health Technology Assessment summary
- Horizon scanning
- Orphan and ultra-orphan medicines
- One Wales and IPFR
- Free of charge policy
- Future challenges



Appraisal Summary



- 27 appraisals between November 2017 and December 2018
- Median time of 17 weeks from agreeing the scope to AWMSG decision
- 25 (93%) received positive recommendations.....

BUT



Statements of Advice

Year (Apr – Mar)	Number of potential missed opportunities
2013-14	55
2014-15	40
2015-16	56
2016-17	39
2017-18	48



Recent Developments

- Updates to Assessment Report (ASAR)
 - Summary table introduced
 - Increased information on views of clinical experts incorporated
 - Table of acquisition costs removed
 - Wider sensitivity analyses (from 5% to 95%) for medicines where the comparator has an associated patient access scheme
- Change made to improve and relay the decision making process of NMG
- Increased use of 'the Vault' to transfer confidential information
- Company feedback form recently introduced – positive responses received so far



Recent developments cont.

- Appointment of AWTTTC Health Economist
- Launch of the AWTTTC Newsletter
- Launch of social media (@AWTTTCcomms)
- Change in AWMSG and NMG Chair

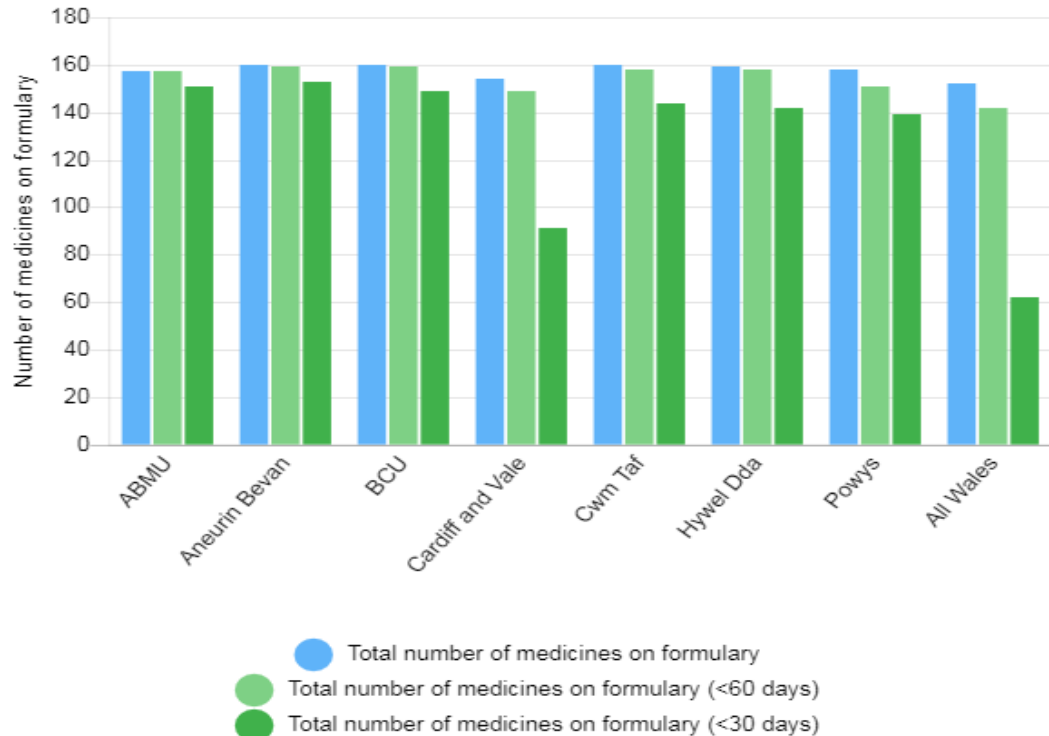


NTF Dashboard

Total potential medicines to be added to formulary

161

Number of medicines on formulary



A photograph of a sunset over a vast, dark blue ocean. The sky is filled with horizontal bands of orange, yellow, and purple clouds. The sun is a bright orange orb just above the horizon line. The text "HORIZON SCANNING" is centered in the upper half of the image in a white, bold, sans-serif font.

HORIZON SCANNING

Horizon scanning developments

- Early identification of medicines which are likely to have a high financial impact or will impact on clinical services is essential for service planning
- Horizon scanning team within AWTTC strengthened
- Horizon scanning now included in the remit of the Medicines Financial Forecasting Prescribing Group
- Improved links with NICE: commentator emails and NICE BIT

Horizon scanning future plans

- Develop a list of all new medicines which may have an impact on NHS Wales for 2019/20
- Strengthen input from clinical networks to improve robustness of information
- Continue to liaise closely with NICE and SMC
- Monitor developments at a pan European level



Orphan and Ultra-Orphan Medicines



- Policy updated in 2015
- 27 medicines eligible medicines between September 2015 and December 2018
- 18 (67%) would not have been eligible previously
- 5 (19%) assessed via the Clinician and Patient Involvement Group (CAPIG)
- 24 medicines (89%) approved under the new policy



One Wales Interim Commissioning and IPFR update

One Wales Interim Commissioning

- Introduced in 2016 to provide conditional approval for licensed or off-label medicines for which there is a clearly defined cohort of patients in Wales
- Suitable medicines identified via clinical networks, Chief Pharmacists, Medicines and Therapeutics committees and IPFR cohort data
- Interim Pathways Commissioning Group make a recommendation by majority vote. The recommendation is considered by NHS Wales Chief Executives.

Progress to date

- Ten medicines have been assessed, nine recommended and one not recommended
- One recommendation has been fully superseded by NICE advice and two partially superseded by NICE and AWMSG advice
- Nine recommendations have been reviewed at least once, outcome data provided by clinicians are presented as part of each review
- Information, including medicines which have been flagged and subsequently not considered suitable for the One Wales process are listed on the AWTTC website

Current One Wales Interim Commissioning Decisions

In this section

1. [Current One Wales Interim Commissioning Decisions](#)
2. [Consideration of medicines and work programmes](#)
3. [Interim Pathways Commissioning Group \(IPCG\)](#)

Interim Pathways Commissioning Group (IPCG) recommendations endorsed by health board Chief Executives

- ✓ **ONE WALES INTERIM COMMISSIONING DECISION SUPERSEDED BY NICE GUIDANCE.** Adalimumab (Humira®) for the treatment of adult patients with severe refractory non-infectious uveitis. October 2016.
- ✓ **ONE WALES INTERIM COMMISSIONING DECISION PARTIALLY SUPERSEDED BY AWMSC ADVICE.** Adalimumab (Humira®) is supported for the treatment of paediatric patients with severe refractory non-infectious uveitis. Reviewed November 2017.
- ✓ **ONE WALES INTERIM COMMISSIONING DECISION PARTIALLY SUPERSEDED BY NICE GUIDANCE.** Arsenic trioxide (TRISENDO™) in combination with all-trans retinoic acid is supported for the first-line treatment of acute promyelocytic leukaemia in adult patients unsuitable for all-trans-retinoic-acid-based therapy. Reviewed February 2018.
- ✓ **Avastin (Bevacizumab) is supported for the treatment of advanced renal cell carcinoma after failure**



About us

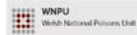
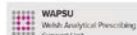
[One Wales Interim Commissioning Process](#)

[Health Technology Assessment \(HTA\)](#)

[All Wales free of charge medicine supply policy](#)

[Resources](#)

[Contact us](#)


AWTTC

 All Wales Therapeutics & Toxicology Centre
 Canolfan Therapiwtteg a Throcsioleg Cymru Gyfan

Medicine requests for consideration for One Wales Interim Commissioning

We welcome suggestions for medicines to be considered via the One Wales Interim Commissioning process from Individual Patient Funding Request (IPFR) panels, Welsh Health Specialised Services Committee (WHSSC), clinicians (ideally through clinical networks), chief pharmacists, formulary pharmacists or medicines and therapeutics committees. The process is driven by identification of unmet clinical need by the service and therefore we cannot accept requests from pharmaceutical companies or from members of the public.

Medicines considered for the One Wales process may be:

- Newly licensed medicines or new indications of existing medicines, ahead of appraisal by the National Institute for Health and Care Excellence (NICE) or the All Wales Medicines Strategy Group (AWMSG).
- Medicines being used outside of their product licence ('off-label').
- The use of a medicine outside of the accepted treatment pathway i.e. the specific sequence of treatment(s) has not been approved by NICE or AWMSG.

For all medicines:

- There should be a clearly defined, specific cohort of patients rather than an individual patient.
- There is a clearly identified clinical need.
- There is a commitment by practising clinicians/clinical networks to capture and collate patient outcome data.

For licensed medicines:

- Medicines with a negative recommendation for use for that indication from the National Institute for Health and Care Excellence (NICE) or the All Wales Medicines Strategy group (AWMSG) will not be considered.
- There should be a clear and binding commitment to engagement in a future health technology appraisal (HTA) by the Marketing Authorisation (MA) holder.
- The MA holder has agreed to provide appropriate evidence (quality, efficacy, efficiency, clinical and cost-effectiveness).

HTA will always be the preferred route for consideration of newly licensed medicines and if it is deemed that


AWTTC

 All Wales Therapeutics & Toxicology Centre
 Canolfan Therapiwtteg a Throcsioleg Cymru Gyfan

Medicines not considered suitable for the One Wales Interim Commissioning Process October 2018

Medicine	Indication	One Wales decision rationale*	AWMSG Steering Committee Date
Apresolol (Oston®)	Rheumatoid psoriatic arthritis	NICE recommended, all IPFR requests pre NICE advice	25/04/2016
Arsenic trioxide (TRISENDO™)	Acute promyelocytic leukaemia (refractory/refractory)	On consultation with experts there is no unmet clinical need for this licensed indication.	22/09/2016
Alonevatin (Bapto™)	Hypertrophic cardiomyopathy	No unmet clinical need identified.	04/07/2017
Belimumab (Benlysta™)	Systemic lupus erythematosus (SLE)	NICE restricted recommendation, TA192, published June 2016.	15/08/2017
Bendamustine	Multiple myeloma (3rd and 4th line)	Licensed alternative (pomalidomide) recommended by AWMSG, Aug 2015. Monitor for further requests, 2018 recommendation.	22/09/2016
Bravecto™ (Bravecto™)	Carcinoma of cervix	HTA in progress with AWMSG	17/12/2016
Bravecto™ (Avastin™)	Ovarian cancer 2nd and 3rd line	AWMSG HTA pending	22/09/2016
Bravecto™ (Avastin™)	Colorectal cancer	NICE negative recommendation	21/05/2016

*The rationale relates to the decision made at the AWMSG Steering Committee meeting and includes NICE and AWMSG appraisal statuses at that time which may have subsequently changed. Please refer to [AWMSG](#) and [NICE](#) websites for current appraisal advice.

Page 1 of 4



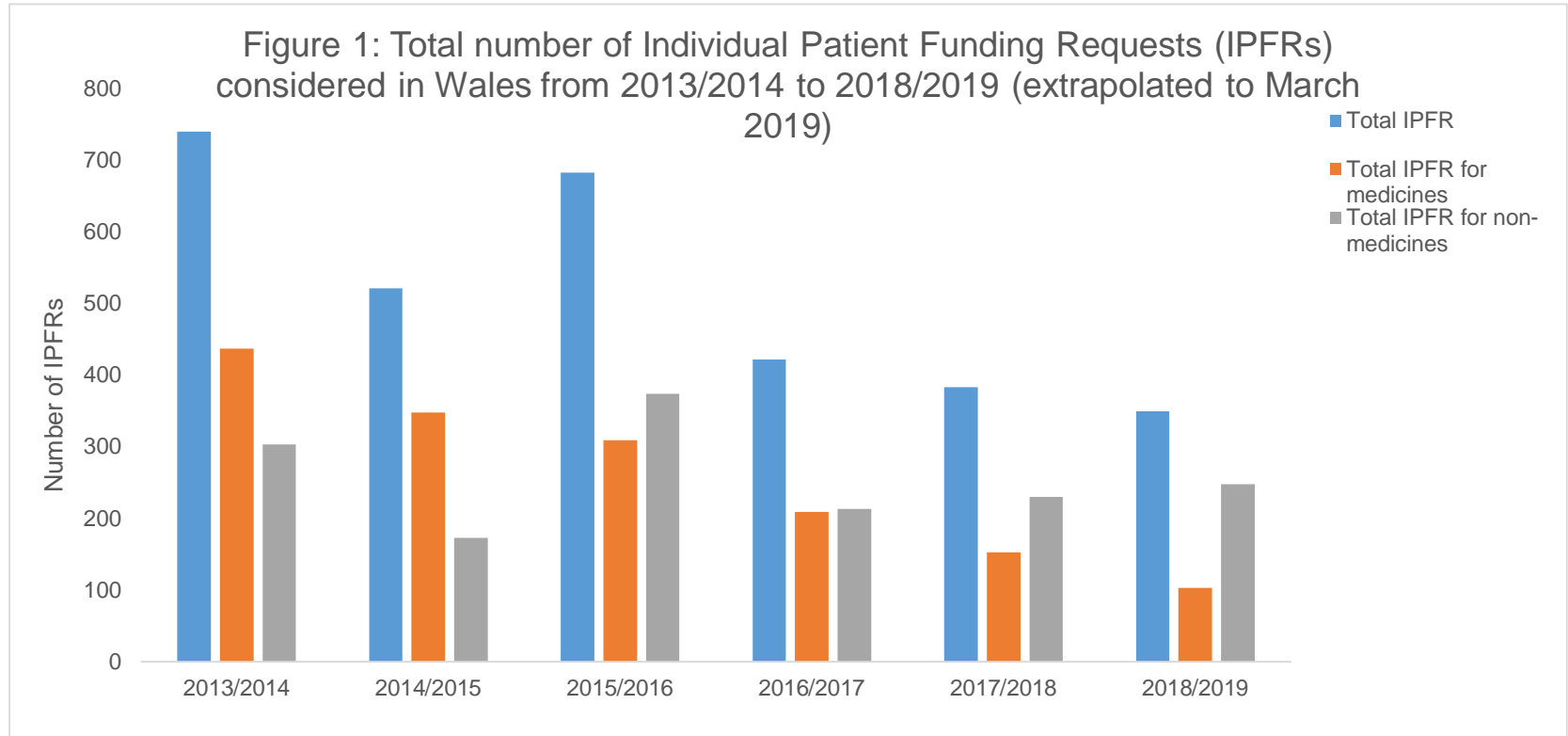
PAMS
Patient Access to Medicines Service
Pwycedd CMed at Wassesteth Meddyrpsistethau

Medicines not considered suitable for the One Wales Interim Commissioning Process October 2018 continued



<https://www.awttc.org/pams/one-wales-interim-commissioning-process>

Total IPFRs are decreasing year on year



Individual Patient Funding Request (IPFR) recent developments

- Since March 2015 AWTTC has worked with IPFR panels and WHSSC to implement recommendations from an independent review to strengthen and improve the IPFR process in Wales
- In October 2016 a new All Wales IPFR database was launched
- In January 2018 the first meeting of the IPFR quality assurance group was held
- Electronic submission of IPFRs went live in July 2018
- Evidence summary template developed
- A video for patients and clinicians explaining the IPFR process is available on the AWTTC website:



More information including the IPFR video can be found at <https://www.awttc.org/ipfr>

All Wales Free of Charge


Why?

Not all health boards and Trusts:

- offered the same arrangement
- aware of such arrangements
- accepted the offer.

What will the process achieve?

Ensures equity and consistency in patient and clinician access to medicines offered free of charge to NHS Wales



AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapwteg a Thocsioleg Cymru Gyfan

All Wales policy - free of charge medicine supply

Purpose

This policy introduces new controls to ensure equity and consistency in patient and clinician access to medicines offered to NHS Wales as free of charge in the following circumstance:

- Newly licensed medicine, where the marketing authorisation holder has engaged in health technology assessment (HTA) by the National Institute for Health and Care Excellence (NICE) or AWMSC, and where the recommendation remains outstanding.

Background

HTA by NICE or AWMSC remains the preferred approach for advising on the clinical-effectiveness and cost-effectiveness of newly licensed medicines. Pharmaceutical companies must continue to be strongly encouraged to engage promptly in the HTA process. It is not our intention to undermine the well-established and accepted HTA and individual patient funding request (IPFR) processes by producing this policy, but to complement those processes.

In the absence of, or whilst awaiting publication of HTA guidance, some pharmaceutical companies have offered NHS Wales a free of charge medicine supply agreement to enable patients and clinicians access to a particular medicine at no cost. Inequity and inconsistency in patient access to medicines may arise when not all health boards/trusts and the Welsh Health Specialised Services Committee (WHSSC):

- are offered the same access arrangement,
- are aware that an opportunity for such access exists,
- accept the offer.

Criteria

1. The Chief Pharmacist Peer Group will consider the appropriateness of every free of charge medicine supply agreement offered by marketing authorisation holders.
2. Each offer from a marketing authorisation holder would be expected to satisfy the following criteria:
 - The medicine has been submitted for HTA by NICE or AWMSC, but a significant delay (e.g. over 6 months) is anticipated before HTA guidance is expected.

Version 3 – Prepared by AWTTC February 2018 Page 1

PAMS
Patient Access to Medicines Service
Meddydd Cefn at allan@nhs.uk/0300 300 3000



All Wales Free of Charge *cont...*

Criteria?

- Newly licensed medicines, where the MA holder has engaged in HTA and the recommendation remains outstanding.
 - MA holders must supply the medicine free of charge until implementation of HTA advice or for as long as the patient(s) require it on clinical grounds if HTA advice is negative
- No significant additional administration costs e.g. testing, monitoring
- Fully free of charge and not a partial discount
- Not intended to undermine well established and accepted HTA and IPFR process

Who makes the decision?

- A majority vote from the Chief Pharmacist Peer Group, with representation from all health boards and Trusts in Wales



Upcoming changes and challenges

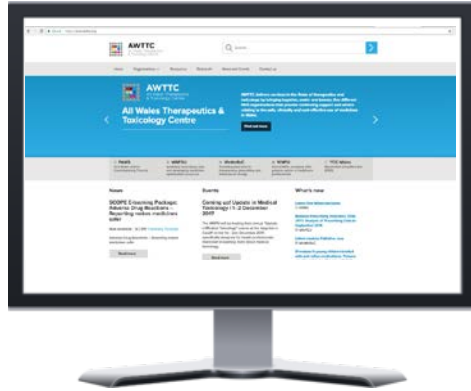
- Brexit.....
- Changes within NICE e.g. increase in capacity for HTA/HST, NICE proposals to charge companies for submission
- Increased number of ATMPs coming to market
- Improve engagement in AWMSG process
- Maintaining transparency: Challenges of appraising medicines where the comparator has a PAS
- Orphan/Ultra-orphan policy update
- Horizon scanning
- Refresh AWMSG website
- 'Hot topics'



***‘Change is the law of life.
And those who look only
to the past or present
are certain to miss the
future’***



Thank you



AWTTC website:
www.awttc.org

AWMSG website:
www.awmsg.org

