2017/18 update – what's changed?

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Outline

- Summary of recent recommendations
- Results of orphan/ultra-orphan review
- New developments and challenges

Appraisal Summary

- 19 appraisals between November 2017 and October 2018
- 17 (90%) received positive recommendations
- Median time from agreeing scope to AWMSG decision was 17 weeks……

BUT

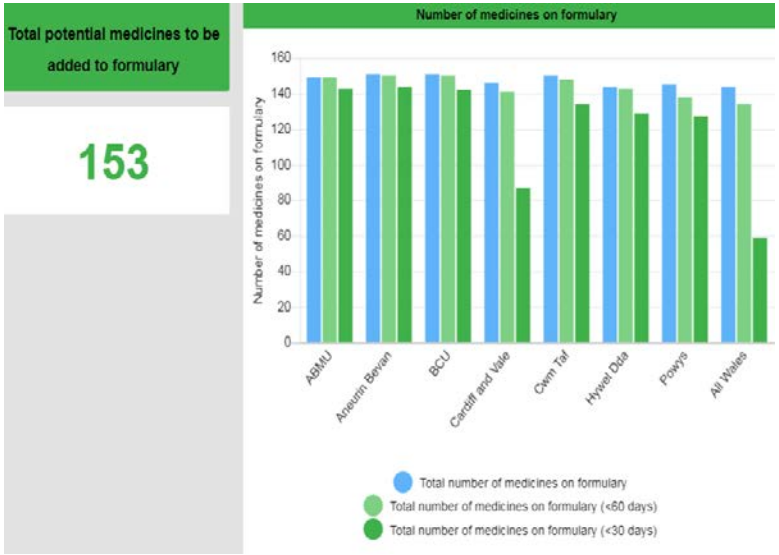
Receipt of Form A to AWMSG Decision 1st November 17– 31st October 18

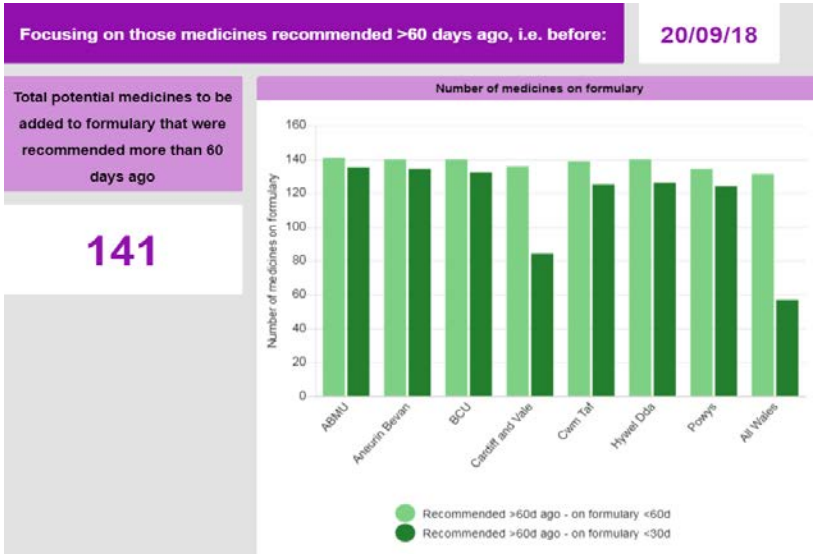
	Months, median	Months, range
Form A received - AWMSG decision	9.3	4.5 to 35.9

Statements of Advice

Year	Number
2013-14	55
2014-15	40
2015-16	56
2016-17	39
2017-18	48

New Treatment Fund - dashboard





Data as of 19th November 2018; 13:25

Orphan and Ultra-Orphan Medicines Appraisals

- Process was updated in 2015
- September 2015 and October 2018, 25 medicines qualified
- 16 (64%) would not have been eligible previously
- 5 assessed via the Clinician and Patient Involvement Group (CAPIG)
- 22 medicines (88%) approved under the new policy (62% approved between 2002 and 2014)

New developments

- Change in AWMSG and NMG Chair
- New Assessment Report template
- All Wales Free of Charge Policy

AWMSG and NMG Chairs

Professor John Watkins

Dr James Coulson

Changes in HTA process

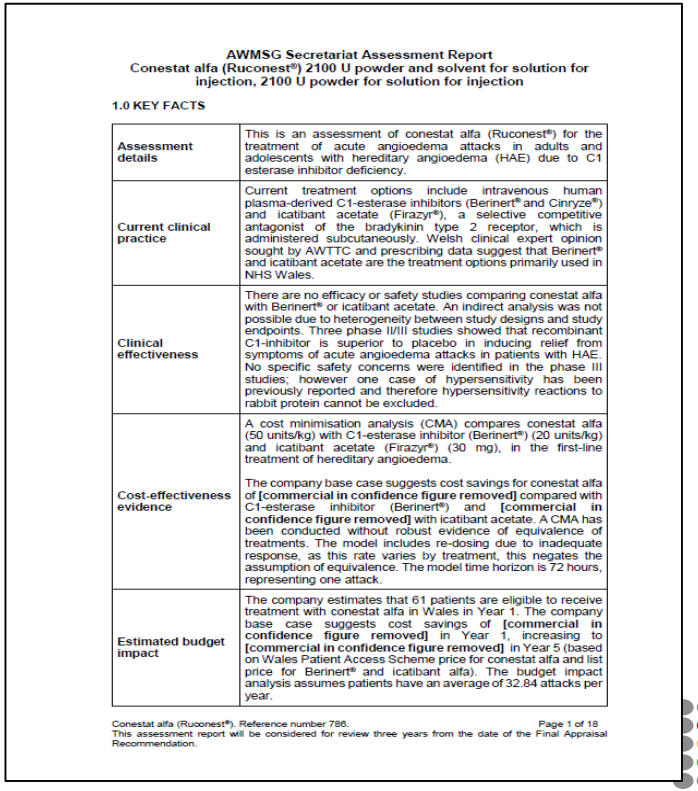
- Updates to ASAR
  - Summary table introduced
  - Table of acquisition costs removed
  - Increased information on views of clinical experts incorporated
  - Wider sensitivity analyses (from 5% to 95%) for medicines where the comparator has an associated patient access scheme

- 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

AWMSG Secretariat Appraisal Report

1.0 KEY FACTS

Assessment details	
Current clinical practice	
Clinical effectiveness	
Cost-effectiveness evidence	
Estimated budget impact	
Additional factors to consider	



AWMSG Secretariat Assessment Report
Conestat alfa (Ruconest®) 2100 U powder and solvent for solution for injection, 2100 U powder for solution for injection

1.0 KEY FACTS

Assessment details	This is an assessment of conestat alfa (Ruconest®) for the treatment of acute angioedema attacks in adults and adolescents with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.
Current clinical practice	Current treatment options include intravenous human plasma-derived C1-esterase inhibitors (Berinert® and Cinryze®) and icatibant acetate (Firazyr®), a selective competitive antagonist of the bradykinin type 2 receptor, which is administered subcutaneously. Welsh clinical expert opinion sought by AWTTC and prescribing data suggest that Berinert® and icatibant acetate are the treatment options primarily used in NHS Wales.
Clinical effectiveness	There are no efficacy or safety studies comparing conestat alfa with Berinert® or icatibant acetate. An indirect analysis was not possible due to heterogeneity between study designs and study endpoints. Three phase II/III studies showed that recombinant C1-inhibitor is superior to placebo in inducing relief from symptoms of acute angioedema attacks in patients with HAE. No specific safety concerns were identified in the phase III studies; however one case of hypersensitivity has been previously reported and therefore hypersensitivity reactions to rabbit protein cannot be excluded.
Cost-effectiveness evidence	A cost minimisation analysis (CMA) compares conestat alfa (50 units/kg) with C1-esterase inhibitor (Berinert®) (20 units/kg) and icatibant acetate (Firazyr®) (30 mg), in the first-line treatment of hereditary angioedema. The company base case suggests cost savings for conestat alfa of **[commercial in confidence figure removed]** compared with C1-esterase inhibitor (Berinert®) and **[commercial in confidence figure removed]** with icatibant acetate. A CMA has been conducted without robust evidence of equivalence of treatments. The model includes re-dosing due to inadequate response, as this rate varies by treatment, this negates the assumption of equivalence. The model time horizon is 72 hours, representing one attack.
Estimated budget impact	The company estimates that 61 patients are eligible to receive treatment with conestat alfa in Wales in Year 1. The company base case suggests cost savings of **[commercial in confidence figure removed]** in Year 1, increasing to **[commercial in confidence figure removed]** in Year 5 (based on Wales Patient Access Scheme price for conestat alfa and list price for Berinert® and icatibant alfa). The budget impact analysis assumes patients have an average of 32.84 attacks per year.

All Wales Free of Charge

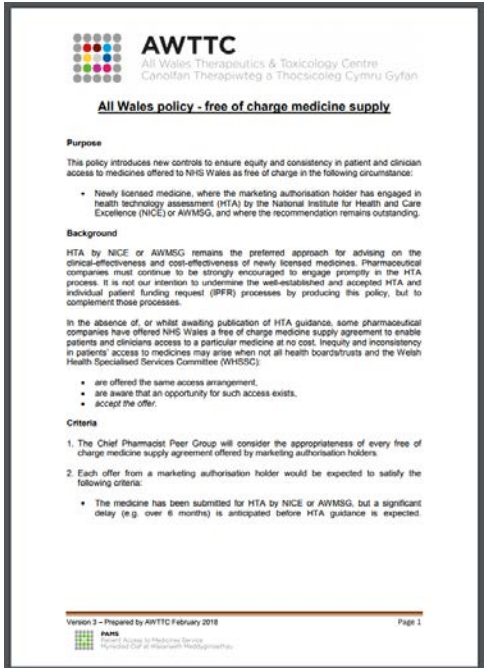
Why?

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 Therapiwteg a Thocsicoleg 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 AWMSG, and where the recommendation remains outstanding.

Background

HTA by NICE or AWMSG 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 patients' 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 AWMSG, but a significant delay (e.g. over 6 months) is anticipated before HTA guidance is expected.

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PAMS Patient Access to Medicines Service

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

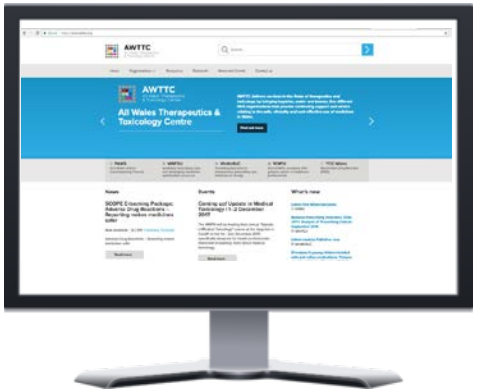
Who makes the decision?

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

Upcoming changes and challenges

- NICE increase in capacity for HTA/HST – affects on AWMSG?
- NICE proposals to charge companies for submission
- Increased number of ATMPs coming to market
- Improve engagement in AWMSG process
- Challenges of appraising medicines where the comparator has a PAS
- Review of orphan/Ultra-orphan policy
- Horizon scanning
- Update AWMSG website

Thank you



AWTTC website:
www.awttc.org

AWMSG website:
www.awmsg.org