The Appraisal Process and Recent Updates

Tony Williams

All Wales Therapeutics and Toxicology Centre

AWTTC
All Wales Therapeutics & Toxicology Centre


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Outline

- Summary of recent recommendations
- Orphan/ultra-orphan and end-of-life medicines
- One Wales interim commissioning funding process
- New developments
- Challenges

Appraisal Summary

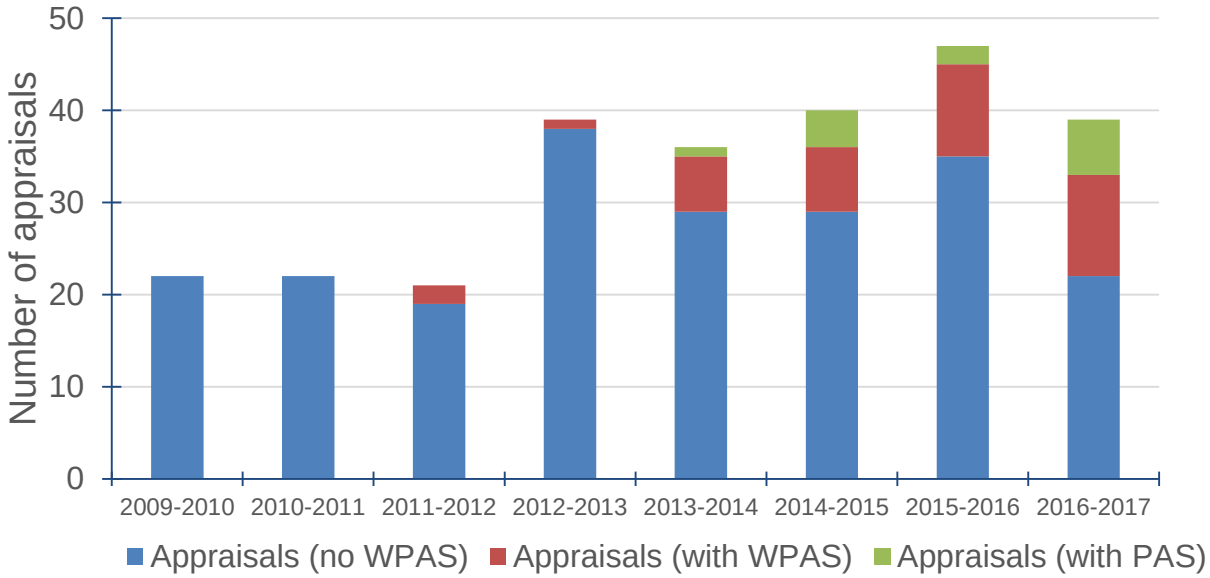
- 55 appraisals between April 2016 – November 2017
- 47 (85%) received positive recommendations
- Median time from agreeing scope to AWMSG decision was 19 weeks……

BUT

Receipt of Form A to AWMSG Decision
1st Apr 16 – 1st Nov 17

	Months, median	Months, range
Form A received - AWMSG decision	10.7	5.3 to 95.9

AWMSG appraisal with a Patient Access Scheme



Statements of Advice

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

No. of Statements of Advice from April to November 2017 = 41

Orphan and Ultra-Orphan Medicines Appraisals

- Policy for appraising medicines that treat rare diseases was updated in 2015 to give patients and clinicians a stronger voice in AWMSG decision making
- Between September 2015 and May 2017 AWMSG has appraised 16 medicines which have qualified under the new process
- 11 medicines would not have been considered eligible for consideration under the previous AWMSG policy
- 5 medicines assessed via the Clinician and Patient Involvement Group (CAPIG)
- 14 of the medicines (87.5%) approved - 62% approved between 2002 and 2014

End-of-life medicines

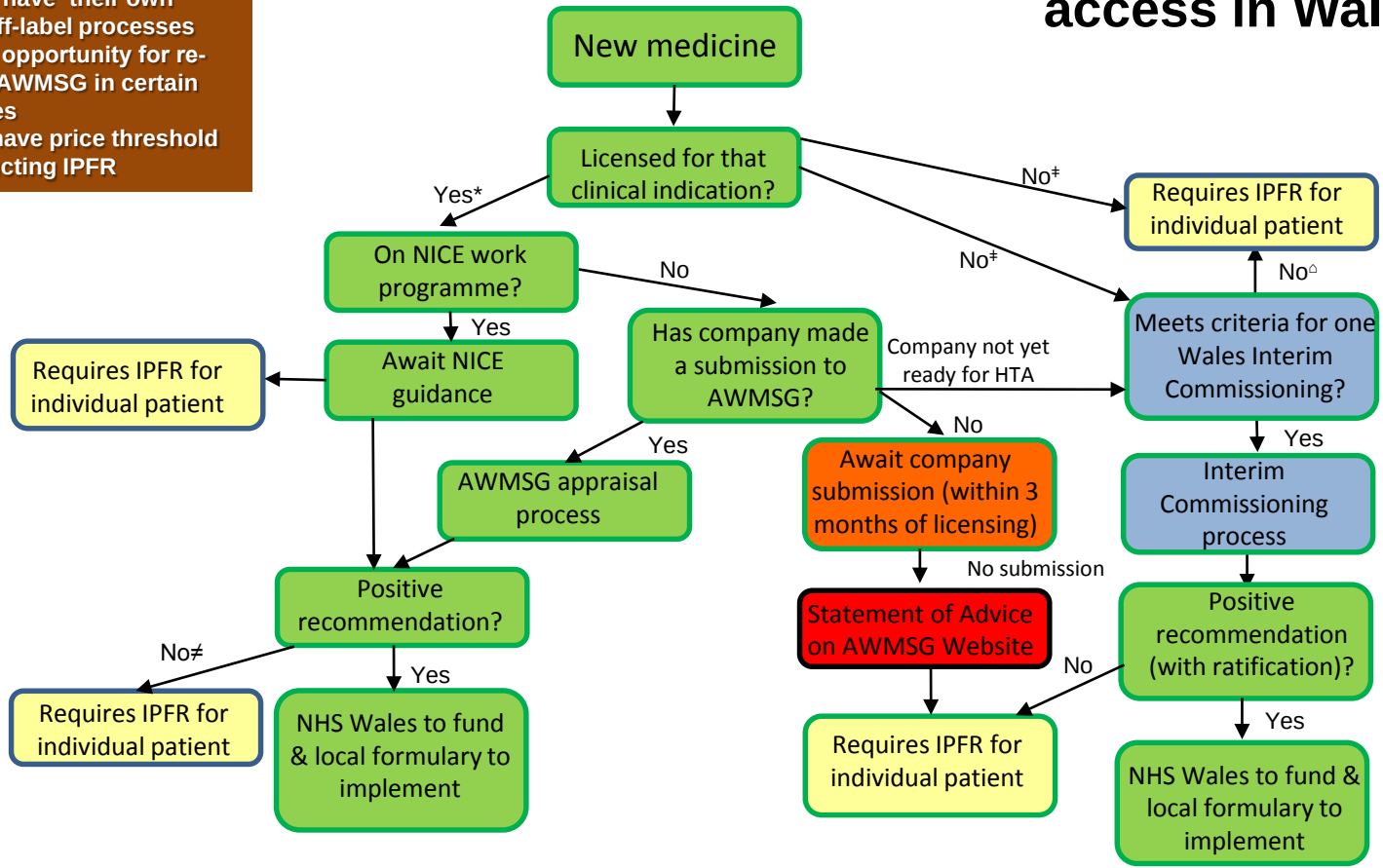
- Based on NICE end of life criteria
- 1 medicine appraised and recommended in 2015 (ahead of NICE advice)
- 2 medicines appraised and recommended in 2016 (one ahead of NICE)
- Nil so far in 2017

AWMSG and NICE Advice

- Between April 2016 and November 2017 **five** medicines appraised by AWMSG have subsequently been appraised by NICE
- **Four** medicines recommended by AWMSG were also recommended by NICE
- Median time of 7.9 months ahead of NICE advice: range 2.3 to 17.3 months

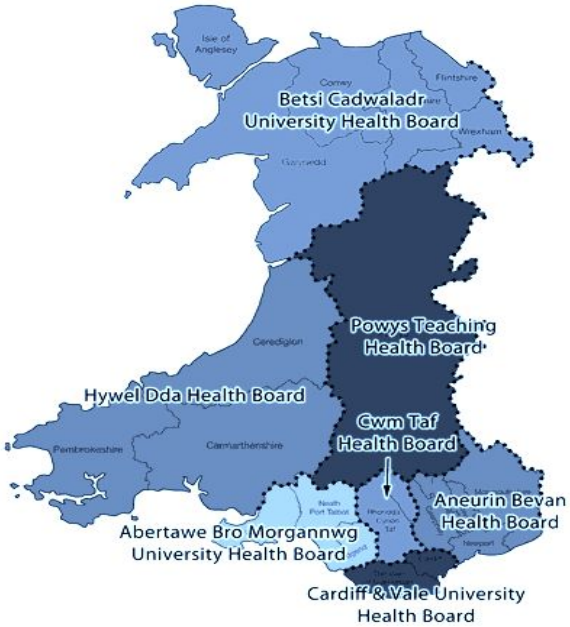
Pathways to medicines access in Wales

- * There is the facility to appraise before NICE if directed
- ǂ =Some HBs have their own unlicensed/off-label processes
- ≠ There is an opportunity for re-appraisal by AWMSG in certain circumstances
- ⌂ Some HBs have price threshold before conducting IPFR



One Wales: Summary

- Plugs a gap – Interim decisions
- Addresses an unmet need
- Weaker evidence base
- Is not an alternative to HTA
- Reviewed regularly
- Patient outcomes



The One Wales Interim Pathways Commissioning Process 2016-17

Medicine	Indication	Ratified	Comments
Adalimumab (Humira)	Treatment of adult patients with severe refractory non-infectious uveitis	Oct 2016	One Wales advice superseded by NICE advice (July 2017)
Adalimumab (Humira)	Treatment of paediatric patients with severe refractory non-infectious uveitis	Oct 2016	Advice interim to AWMSG advice (appraisal in progress, advice expected February 2018). Currently undergoing review
Arsenic trioxide	First line treatment of acute promyelocytic leukaemia	Oct 2016	Has received licence for this indication. Manufacturer requested to engage in AWMSG appraisal. Currently undergoing review
Denosumab	Treatment of osteoporosis in men at increased risk of fractures	Mar 2017	Advice interim to NICE MTA (due March 2019)
Docetaxel	In combination with androgen deprivation therapy, can be made available for the treatment of men with hormone-naive metastatic prostate cancer	Aug 2016	Abiraterone due to be licensed in 2018 for this indication, with NICE advice following in Sept. 2018. Review decision (October 2017): continue availability
Rituximab (Mabthera)	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	Jul 2017	Licence pending 2019, will then be eligible for appraisal via HTA (via NICE or AWMSG)
Axitinib (Inlyta)	Treatment of advanced renal cell carcinoma after failure of prior treatment with pazopanib	Aug 2016	Currently undergoing review
Bevacizumab (Avastin)	At a dose of 7.5 mg/kg in combination with carboplatin and paclitaxel for the front-line treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer	Aug 2016	Currently undergoing re-assessment
Rituximab (Mabthera) + bendamustine	Treatment of indolent lymphomas, first line and relapsed. To include follicular lymphoma, Waldenstrom's and marginal zone lymphoma	Apr 2017	Usage restricted to where standard or HTA-approved medicines not suitable
Rituximab (Mabthera) + bendamustine	Treatment of mantle cell lymphoma, first line and relapsed	Apr 2017	Usage restricted to where standard or HTA-approved medicines not suitable

Benefits to HTA as a result of One Wales process

- Intelligence gathered has strengthened links between HTA and ‘cohort’ requests considered by IPFR panels
- Unmet need/clinical demand highlighted to HTA
- Four medicines have subsequently been identified as appropriate for AWMSG appraisal after being identified as an IPFR cohort

New developments

- Biosimilar position statement
- Strengthened horizon scanning processes/New Treatment Fund
- SHARE discussion forum and the ‘Vault’
- Collaboration at a National and European level via EUnetHTA
- Production of videos to improve engagement and highlight appraisal processes

AWMSG Biosimilar Position Statement

‘AWMSG does not normally appraise biosimilar medicines.

Existing health technology assessment advice for the ‘reference’ medicine, published by AWMSG or NICE, will automatically apply for biosimilar medicines licensed for the same indication and in the same population as the ‘reference’ medicine. In the absence of advice for the ‘reference’ product, the biosimilar medicine is not endorsed for use within NHS Wales.

The marketing authorisation holder of the ‘reference’ or biosimilar medicine is encouraged to engage with AWMSG where there is negative HTA advice or in the absence of advice. Please refer to the AWMSG Process for Industry Engagement for further information.’

All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Access to medicine video

Accessing medicines in Wales

All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Upcoming changes

- Revised template for assessment reports (ASARs)
- Improved horizon scanning processes
- Policy to introduce equity and consistency in patient and clinician access to medicines offered to NHS Wales free of charge

Future challenges

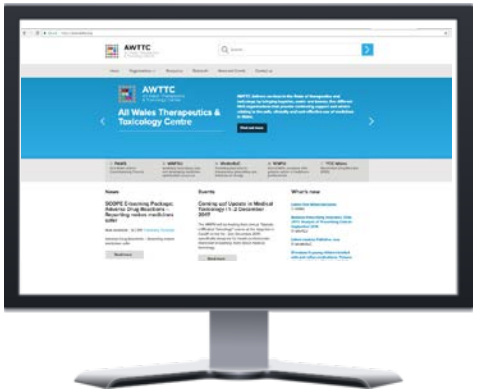
- Impact of changes within NICE
- Increased complexity of medicines in the horizon pipeline e.g. advancements in immunotherapy
- Increasing complexity of access schemes for appraised medicines and their comparators
- Impact of Brexit

Making a good decision

When you make a decision, you need facts. Decision making is simplified if those facts are in your brain (because the submission was clear and the evidence convincing) and at your fingertips. If they're all in the study reports or papers ‘on file’ somewhere, or if the evidence isn’t presented clearly then you may not make the right decision

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

Thank you



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