



Review of AWMSG processes to support medicines access in NHS Wales

Action for AWMSG:

AWMSG is asked to support process changes to improve access to medicines.

Situation:

At a time when the NHS is facing unprecedented pressure and an increase in service demand, the All Wales Medicines Strategy Group (AWMSG) must ensure that it continues to provide value when advising the Welsh Government on medicines for NHS Wales. The National Institute for Health and Care Excellence (NICE) has increased its capacity for technology appraisals and is providing a more streamlined and proportionate approach to its technology appraisal process. This has led to a significant decrease in the number of medicines requiring AWMSG health technology assessment (HTA).

If a medicine is not selected for HTA by NICE, it may be considered by NHS England (NHSE) for national commissioning; or there may be a requirement for local decision-making. The same situation does not apply in Wales as positive HTA has been required for the routine funding of all newly licensed medicines (with a few exceptions as listed in the exclusion criteria).

There have been occasions when AWMSG has been unable to advise on medicines with a perceived clinical need as the company has not engaged with the AWMSG appraisal process. This may be due to the lack of resources required for a company to engage in the HTA process, or there may be a paucity of data to inform a submission or develop a suitable health economic model. This situation can lead to difficulties for the service.

As the healthcare and medicines access landscape evolves and there is a shift towards increased collaboration between UK HTA and regulatory bodies, it is timely for AWMSG to review its current processes. It is essential that AWMSG continues to provide timely advice on medicines where clinical need and health impact is greatest.

Background:

Since 2002, AWMSG has provided HTA recommendations on medicines that have not been included in the NICE work programme, or where there may be a time benefit in issuing advice ahead of NICE. Whilst recognising that HTA is the gold standard for evaluating the clinical effectiveness and cost effectiveness of a medicine, there are occasions when a medicine, with a service benefit and patient need, may fall outside the established scope for HTA (by NICE or AWMSG) whilst being un-suitable for One Wales Medicines Assessment. A route is needed for advising NHS Wales on medicines where no process currently exists. AWMSG must be able to provide timely advice on medicines that are of most value to NHS Wales and ensure clinicians can access medicines for their patients when they need them.

Proposed changes to medicines access processes:

AWTTC has reviewed current processes and propose the following changes:

1. AWMSG will adopt *inclusion* criteria for assessment instead of *exclusion* criteria and provide advice on medicines where there is a **clear identified clinical need and/or benefit to patients and NHS Wales**.

2. Statements of advice will no longer be routinely issued for new medicines/licence extensions not on the NICE or AWMSG work programme.

3. AWMSG will no longer routinely appraise minor licence extensions, including paediatric licence extensions [briefing paper to be considered by AWMSG, May 23].

4. AWTTC will present potential medicines for assessment to a **scrutiny panel who will decide, applying pre-defined criteria, whether a medicine should be assessed by AWMSG and, if so, the most appropriate route for the assessment**. This will include historic statements of advice and HTA advice that may require a review. Engagement with clinical networks, health boards and horizon scanning will be essential in ensuring AWTTC identify the right medicines for consideration by the scrutiny panel.

5. AWTTC will develop an alternative process for assessing medicines which do not fit into existing HTA processes. This will include reviewing the remit of the New Medicines Group and the One Wales Medicines Assessment Group, considering whether an adaption of their roles to accommodate the process changes will be required. Medicines that may meet the AWMSG criteria for alternative routes of assessment include:

- Medicines available or considered for routine commissioning elsewhere in the UK
- Antimicrobial medicines where there is a clinical need for advice in Wales
- Biosimilar medicines in line with the biosimilar strategy
- Medicines which require a review; these may represent the standard of care for a particular indication, be included in national clinical guidelines or be associated with a significant reduction in cost.