Inclusion of NICE guidance into local formularies

Adam Hill

Recent guidance from NICE requires that NICE-approved medicines must be automatically included into local formularies.

The National Institute for Health and Care Excellence’s (NICE’s) guidance on good practice for creating local formularies sets out for the first time exactly what is expected of decision makers in charge of prescribing, handling and commissioning medicines.

Published in December, the document Developing and Updating Local Formularies (http://bit.ly/ZDLoCX) aims to bring uniformity to a process that previously had none.

NICE insists that this lack of standardisation has in the past led to regional anomalies, and the idea is that from now on existing formularies or proposed new ones will avoid duplicating effort and become more transparent.

The stated aim is to help create formularies ‘that reflect local needs, reduce variation in prescribing, and allow rapid uptake of innovative medicines and treatments’.

Written for the NHS in England – but also applicable to formularies in Wales – the new guidance contains four key recommendations.

Recommendations

Perhaps the most notable of these is that NICE-approved medicines should automatically go into the local formulary so that they are available for clinicians to prescribe ‘should they choose to’.

The next two state that health providers should not carry out their own investigation into a treatment that NICE has already appraised, nor should they challenge one of NICE’s recommendations.

• include – within 90 days – medicines with a positive NICE technology appraisal into the local formulary automatically, as long as they are clinically appropriate and relevant to the services provided by the organisation
• for drugs where there is an existing NICE technology appraisal, ensure there is no further duplication of the NICE evidence assessment or challenge to an appraisal recommendation
• publish all relevant local formulary information online in a clear, simple and transparent manner, so that patients, the public and stakeholders can easily understand it

Table 1. Summary of the NICE guidance for local formularies

These are both actions – along with not including all NICE-approved drugs – to which formularies have been prone, according to the Department of Health.

Ignoring or challenging NICE guidance blocks or delays the uptake of NICE-approved medicines and such practices have been seen by critics as cost-saving measures. This is, therefore, welcome news for both the pharmaceutical industry, keen for a return on new drugs, and patients, concerned about the ‘postcode lottery’ aspect of local treatment. However, eliminating inconsistency between local formularies is something few would argue with.

Lastly, formulary information should be put online in a form that patients will find easy to follow.

Professor Alan Silman, Director of Research Strategy and Policy, Arthritis Research UK, and chair of the NICE guidance development group, stated: ‘A local health formulary is an important tool in educating and guiding prescribers. The guidance provided in this document allows formularies to continue responding to local needs and circumstances but also ensures that NICE’s decisions to approve an intervention and other appropriate inputs into formulary production are taken up in a timely and transparent manner.’

Yet insisting that drugs with a positive NICE technology appraisal should go straight into the local formulary represents a significant change from current practice.
While no disquiet has been publicly voiced, health professionals may object to NICE-approved drugs being given automatic preference at the expense of established products that have not been considered by the watchdog.

**IHW report**

However, none of this should come as a surprise to prescribers: the *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS (IHW)* report from December 2011 indicated clearly the future direction of government policy.

Following this up in August 2012 chief pharmaceutical officer Dr Keith Ridge wrote a letter (http://bit.ly/ZgaOM9) to NHS acute, mental health and primary care chief pharmacists and strategic health authority pharmacy and prescribing leads, encouraging a review of formulary processes to begin the implementation of IHW.

Healthcare providers and commissioners such as the clinical commissioning groups were expected to have published exactly which NICE technology appraisals are included in their own formularies by 1 April.

Speaking in December, Ridge called on local health systems to use NICE’s guidance to ensure that all formularies ‘are patient focused, outcomes based and support optimised use of medicines’.

The IHW also introduced a NICE compliance regimen for technology appraisals – hence the requirement to incorporate all recommendations automatically ‘in a planned way that supports safe and appropriate clinical practice’. This should be done within 90 days to support the statutory obligation for commissioners to make funding available within three months for NICE-approved drugs.

**NHS Constitution**

All this is underpinned by the NHS Constitution, which is categorical in giving patients the right to receive NICE-approved treatments ‘where appropriate’.

The Constitution also states that the local NHS must look at medicines that have not received the go-ahead from NICE and to make funding decisions ‘rationally following a proper consideration of the evidence’. And if the local NHS decides not to fund a drug or treatment it will have to explain its decision.

The sheer diversity of formularies, ranging from plain lists of drugs to in-depth summaries of evidence linked to local-care pathways and policies, perhaps explains why no definition has been made explicit in the new guidance from NICE.

Instead it refers to ‘the output of processes to support the managed introduction, utilisation or withdrawal of healthcare treatments within a health economy, service or organisation’.

**Conclusion**

The NICE guidance has been summarised in Table 1. The guidance is driven by the imperative of adhering to statutory requirements while reflecting local needs and reducing variation in prescribing.

So for any prescribers wondering how we have arrived at this point the answer is simple: giving patients access quickly to NICE-approved drugs and allowing the rapid uptake of innovative medicines and treatments have both been clearly enshrined in recent legislation. Healthcare providers have been left in no doubt about what the law requires them to do.

**Declaration of interests**

None to declare.

Adam Hill is a freelance writer on health and the pharmaceutical industry.