Improving access to medicines in Wales

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England's controversial Cancer Drugs Fund underwent significant reform in 2016. Stakeholders called for more clarity about what, if any, impact the changes would have in Wales, particularly given NICE's central role in the new-look Fund and the earlier access to evidence-based treatments it is expected to provide. The Welsh Government has stated that patients in Wales will not be treated any less favourably.

As part of its 2016 Compact to Move Wales Forward with Plaid Cymru, the Welsh Government agreed to prioritise work on improving access to medicines in Wales. This included establishing a 'new treatment fund' to support the introduction of innovative medicines, and an independent review of the Individual Patient Funding Request process.

This article summarises the changes to the Cancer Drugs Fund and its relationship with processes in Wales, and provides an update on the Welsh Government's work in this area.

How has the Cancer Drugs Fund changed?

In April 2016, the Cancer Drugs Fund in England was brought under the remit of NICE, with fundamental changes in its operation.

Previously, the Cancer Drugs Fund provided access to cancer medicines which had not been approved by NICE. Whilst the Fund may have improved access to cancer drugs which weren't routinely available in the NHS, it was criticised for failing to demonstrate impact on patient outcomes or value for money. There was general agreement that the Cancer Drugs Fund was unsustainable in that form.

The remodelled Cancer Drugs Fund will be used to support the early introduction of medicines which show promise, but for which more evidence is needed before they can be recommended for routine use. A modified appraisal process for cancer drugs now allows NICE to make one of three recommendations:

– recommended for routine commissioning;

– not recommended for routine commissioning;

– recommended for use within the Cancer Drugs Fund (new).

A medicine will remain in the Cancer Drugs Fund for an agreed period while further evidence is collected. NICE will then make either a positive or negative recommendation for routine commissioning.

How is this relevant to Wales?

The Cancer Drugs Fund is the funding mechanism by which promising new drugs are made available to patients in England.

The same drugs – i.e. those recommended by NICE for use within the new Cancer Drugs Fund model – are also routinely available to Welsh patients. In January 2017, the Cabinet Secretary confirmed that the newly-established New Treatment Fund in Wales will support the introduction of cancer medicines given an interim recommendation by NICE.

The first cancer drug appraised by NICE and recommended for the Cancer Drugs Fund under the new arrangements was osimertinib (Tagrisso™) for lung cancer. Health boards in Wales were instructed to make osimertinib available in accordance with NICE's guidance.

New Treatment Fund

The Welsh Government established its £80 million New Treatment Fund in January 2017. The Fund will provide £16 million each year over a five year period, with the aim of speeding up access to new medicines in Wales.

This applies to medicines – for all health conditions – recommended by NICE or the All Wales Medicines Strategy Group (AWMSG). Medicines which have not been recommended by NICE/AWMSG for use within the NHS will not be supported via the New Treatment Fund. It remains the case that clinicians may be able to apply for

funding for non-recommended medicines through the Individual Patient Funding Request (IPFR) process, where they believe such a treatment will significantly benefit their patient. (See below for more on the IPFR process).

The NHS in Wales already has a legal requirement to fund medicines approved by NICE or AWMSG. The New Treatment Fund seeks to enable health boards to make these medicines available at an earlier stage, within a maximum of two months of the recommendation being published (rather than the previous three month timescale). The Cabinet Secretary told Assembly Members that the Fund will be ring-fenced to ensure it is used for the intended purpose of helping health boards plan sustainably for the introduction of new medicines.

The British Medical Association (BMA) has described the New Treatment Fund's evidence-based approach as 'sensible'. The Fund has also been welcomed by industry. The Association of the British Pharmaceutical Industry (ABPI) stated:

> To the frustration of patients and clinicians, we know that health boards have faced financial challenges in planning for the introduction of innovative treatments. The additional £80 million offered by this New Treatment Fund over five years should overcome these concerns, enabling health boards to be early adopters of all medicines shown to be cost and clinically effective.

Health boards will be expected to report to the Welsh Government on a quarterly basis about their compliance with timescales for the introduction of new medicines. The Cabinet Secretary has committed to update the Assembly about the operation of the New Treatment Fund before the summer recess 2017. (PDF, 179KB)

Individual Patient Funding Request review

The independent review of the Individual Patient Funding Request (IPFR) process in Wales reported in January 2017.

Through the IPFR process, patients may be able to access medicines which haven't been approved for routine NHS use, if their clinician believes this is the best treatment for them. Similar processes exist elsewhere in the UK.

Previously, decisions on IPFRs have been based on a clinician's ability to demonstrate 'clinical exceptionality' in the case of their patient. This was a particular focus of the

review in Wales, which concluded that the exceptionality criteria was poorly understood and should be replaced. The review recommended that IPFR decisions should be based on whether a patient will gain significant clinical benefit from a treatment, and whether the treatment offers reasonable value for money.

The Cabinet Secretary responded to the review in March 2017. He told the Assembly that health boards had already started work to reform the decision-making criteria, and that this should be achieved by May 2017. The rest of the recommendations are expected to be implemented by September 2017. The Cabinet Secretary stated:

> The IPFR process has a place within the policy framework for access to treatment for a relatively small number of individuals. For the majority of the population, we will continue to place the appraisal process at the centre of our evidence-based approach, ensuring people have access to clinically and cost-effective treatment. The new £80 million treatment fund I announced in January supports this approach by providing earlier access to new medicines recommended by NICE or the AWMSG.

Patient representatives have long been calling for more certainty about which treatments are available, and greater clarity about the processes involved. Whilst the establishment of the New Treatment Fund and work to strengthen the IPFR process in Wales have been broadly welcomed, the Welsh Government will need to be able to show how these measures are impacting on patient experience and outcomes, and demonstrating effective use of NHS funds.

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