Update on the Cancer Drugs Fund

As I noted in my post on the NICE committee's recommendation about bosutinib earlier this week, in England the Cancer Drug Fund (CDF) has received a further two years of funding up to the end of March 2016 with a budget of £200 million for each year.

As we all know, three out of the five TKIs for the treatment of adult patients with CML can only be funded if a clinician makes an application to the CDF on behalf of a patient, providing the patient meets certain clinical criteria.

The three TKIs in question (dasatinib, bosutinib & ponatinib) are members of what is rather grandly called the national 'CDF Cohort Policy List'.

For CML patients in England who do not meet the clinical criteria mentioned above, there remains one other route to access the CDF. This is by their clinician making an Individual Funding Request (IFRs) which is now more correctly called an ICDFR.

CML patients with long memories will recall IFRs from the pre CDF era when requests and decisions were made by local PCT panels. For many, those memories will be tinged with bitterness, since that previous decision making process was arbitrary, inconsistent, ill-informed and biased.

Currently the ICDFR system is run on a national basis, although managed supra regionally, in an attempt to eliminate the failings of the pre CDF system.

Even so, the recently published figures for the first quarter (April - June) of the current (annual) CDF, demonstrate how difficult it is for applications to succeed. 30% of applications were unable to qualify for onward referral to the assessment panels, with a further 50% of those applications failing.

Additionally the 'CDF Cohort Policy List' referred to above, operates on the lines of a league table. Each drug accepted on the list is given a 'score' and is subjected to an ongoing evaluation audit. This can result in a drug moving up or down the league table.

Drugs at the lower end of the List are challenged every time an application for a new (drug) entrant is considered by the CDF clinically oriented lead panel. If a new entrant is given a high 'score', drugs already on the List risk being displaced and/or delisted with the result that they will cease to be funded by the CDF (at least as List members).

The rationale is to maintain a dynamic list and, given that the budget is finite, displacement is one means of achieving this objective.

Securing operational excellence over the longer term within this framework will always prove difficult when additional features are factored in.

For example once a patient secures access to a drug via the CDF they achieve what is described as 'protected' status, until they, in consultation with their clinician, decide to cease being treated. The longer the duration of the Fund the greater the likelihood that this 'protected' patient population will gradually absorb an ever larger proportion of the Fund.

Critics of the CDF have not been slow to highlight this issue. They have been joined by others who argue, with some justification, that the Fund is a discriminatory device since it is limited to drugs for cancers alone.

This 'political' feature of the Fund has proved distasteful to those 'policy purists' whose preference is for a single pristine architecture designed for the assessment and appraisal of all drugs for all conditions.

Devotees of what is often referred to as a 'single mechanism' had high hopes that rendering the principle that underpins Value Base Pricing into a set of operational procedures would achieve that objective.

Initially the DH did not argue to the contrary. The current situation, even though we lack any real detail, now looks decidedly different with everyone waiting for the NICE board to sign off the scheme details before publication either at the end of November or early December.

We do know that there will be a consultation period in the first quarter of 2013 when we will be able to make comment. There will be an initial 'shadow' period when the scheme's robustness will be tested by running an initial tranche of drugs through VBP assessment to establish if it is 'fit for purpose'.

Our position at CMSLG is as follows. We support the continuation of the CDF until such time as VBP meets the objectives set for it by the government.

We think we will be in for a long wait for the introduction of a perfect state VBP system and consequent discontinuation of the CDF.

We would also argue that even if perfect state VBP is eventually achieved, it will still fail to address one important feature of the CDF.

Namely that applications to join the CDF List can be made for drugs that have not entered the NICE HTA process, but have nevertheless been officially designated (by the EU EMA) as being safe and able to achieve therapeutic efficacy.

The HTA process can take up to two years before a drug is accepted for routine funding by the NHS. That is a very long time in 'cancer time' and we strongly support cancer patients being given the opportunity to gain access to effective therapies as soon after diagnosis as is feasible.

We also support access for non-cancer patient populations being granted a similar (urgent) access timeline provided their conditions are life threatening, life limiting or debilitating.

Finally, we are of course also aware that VBP is only one part of the story.

Other activity 'upstream', as it is known, is attempting to move the regulatory process (that results in a drug being licensed for use) to a stage where it is sensitive to recent scientific advances.

The same applies to activity 'downstream' to ensure more effective and efficient use of targeted therapies when they are in routine use in the NHS. Homecare medicines, where some patients receive their drugs by courier, fall in this category.

David Ryner
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