Access to newly licenced medicines

Beating Bowel Cancer

A ‘Triple lock’ clinical option
Securing fair patient access to cancer medicines in Scotland

Two important principles for fair drug access are:

- there is a presumption in favour of granting patients access to medicines in Scotland based on clinical need, whatever their age, or wherever they may live and;
- that all clinicians should be given the freedom to prescribe in the confidence that their recommendation will be upheld by the IPTR Panels.

Time is not of the side of cancer patients. All sides of the political spectrum acknowledge that there is a problem and a need for immediate reform. There is recognition that Scotland’s cancer patients need to see a change in the system without delay.

It is hoped that the solution outlined will give them certainty that decisions will be made quickly and efficiently. By proposing improvements to the Individual Patient Treatment Request (IPTR) system which puts the patient’s clinician at the centre of the decision making process then patients will have absolute confidence that the decisions made through it relate purely to clinical need rather than consideration of cost.

To that end, and in conjunction with the implementation of other recommendations in the NMR that will improve transparency overall, we would ask the Cabinet Secretary to implement a ‘Triple-Lock’ Clinical Opinion option for all IPTR requests.

Implementing the ‘Triple-Lock’ model would be possible in the immediate term as an extension of the measures being brought forward by the Scottish Government in the wake of the New Medicines Reviews.

The ‘Triple-Lock’ principle would be used to ensure that IPTR applications demonstrate clearly that the recommendation for treatment is backed incontroversibly by the weight of a patient’s doctor’s medical opinion, irrespective of cost. This would provide a relatively low-cost improvement to the IPTR system that would ensure that it is led by the expectations of specialist doctors and the interests of their patients.

Rather than requiring clinicians to prove that the case they are describing is ‘exceptional’ and therefore exceptionally likely to benefit to the treatment in question – a stipulation that patients often tell us is only possible to fulfil after they have tried the drug – the ‘Triple-Lock’ relies on a valid presumption that a patient’s personal clinician is the best judge of whether a treatment is likely to work.
By ensuring that IPTR applications are subject to a presumption of approval if they can be vouched for in advance by more than one specialist clinicians, we anticipate that the 40% of treatment requests currently rejected will be reduced or eliminated altogether, while patient appeals against IPTR decisions will also be minimised.

Outline of the ‘Triple lock’ clinical option

The picture is clear: for bowel cancer patients across Scotland, securing fair access to drugs can be a lengthy, confusing and frustrating experience.

The first question that comes to bowel cancer patients’ minds after diagnosis is not “will I survive?” Instead they ask “what are my options?”. Unfortunately, the first barrier that patients face is often the lack of readiness by their doctors to inform them that crucial drugs therapies may be an option, even though they are not sanctioned for use in Scotland by the SMC. Many doctors are reluctant to make an IPTR application purely on an assumption that it will not succeed.

A clinician should be given the freedom to discuss with their patients all the available treatment choices available to them. More must be done to ensure that specialist clinicians make patients aware of all the treatment options that are clinically appropriate, including access to medicines licensed by NICE, but not recommended for widespread use in Scotland by the SMC.

The system would be designed to give all sides confidence:

- Patients would be confident that drug treatments will be made available to them if that is the course recommended by the clinical opinion of doctors who know their case in detail and who are not guided by consideration of cost
- Clinicians would be confident that the IPTR applications that they make on behalf of patients are backed by peer review and will be approved by the IPTR panel
- NHS boards would be confident that their decisions over IPTR requests would no longer be subject to lengthy appeals by patients questioning the reason for their judgement.

So how would this work in practice?

As discussed above, if a specialist clinician decides that a non-SMC approved medicine will be beneficial to the patient, and the patient agrees that the option presented is worth pursuing, then the doctor must be prepared to assist the patient to make a full IPTR request. As is currently the case, the patient’s specialist clinician will only agree to submit an IPTR application if, in their professional opinion, the therapy requested is likely to deliver direct benefits to the patient’s length and / or quality of life.

1. In addition, the patient’s clinician must submit the completed IPTR application for peer review by two specialists in the relevant clinical field who are qualified to offer an objective second opinion on its
merits. These clinicians would come from a third party NHS health board and be selected from a pool of practicing clinicians independent from the SMC. Their task would be to quickly and efficiently assess the merits of the original application and state whether they recommend its submission to the relevant IPTR panel on the basis of medical efficacy alone.

2. If, upon examining the merits of the original IPTR application, the supporting clinicians agree that the prescribed treatment is likely to deliver the benefits described, then their opinions are included with the application and submitted to the IPTR board.

3. The inclusion of two positive supporting statements in addition to the opinion of the patient’s personal clinician, would deliver a ‘Triple-Lock’ for the IPTR application and result in a presumption of approval for the recommended treatment by the IPTR panel.

4. The inclusion of conflicting support statements by the reviewing clinicians would mean that the IPTR panel would be asked to consider the application on the basis of ‘Double-Lock’ supporting evidence. This circumstance would still result in a presumption in favour of approval by the IPTR panel. However, the drug would be approved subject to short-term review of clinical efficacy in the early stages of the treatment course that would determine whether the therapy should continue in the longer term.

5. In addition, every treatment approved by the IPTR process would be subject to clinical review after a time period set by the IPTR panel. This would ensure that the efficacy of the treatment can be objectively assessed in reference to the results achieved.

6. It would therefore be essential that every IPTR panel considering both applications and reviews must include one or more specialist clinicians with expertise in the condition to which the treatment application relates.

7. If neither independent supporting clinician chose to support the IPTR application, the treatment request would go no further, meaning that the patient would have to explore alternative treatments without making any formal submission to the IPTR panel.

**Budgetary implications**

It is important to note that while the overall number of IPTR applications may rise as a result of increased knowledge of the process by patients and clinicians (an outcome that is likely as a result of current recommendations in the NMR), the quality of applications would improve, meaning that only those most likely to benefit from treatments will receive them.
We anticipate that there would be a relatively small increase in treatment costs for NHS boards as a result of the expansion of access to drugs for both primary and secondary care, due to the likely increase in the numbers of patients making successful IPTR requests. However, this would be further controlled by the implementation of post IPTR treatment efficacy reviews, as described above.

In order to enable health boards to ensure that the additional access by individual patients to medicine therapies through the IPTR process does not disrupt annual planning for drug budgets, we would advise the creation of a closely audited central drug fund for application to resources by all health boards in Scotland.

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Beating Bowel Cancer

30 May 2013