Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE's technology appraisal and highly specialised technologies programmes – a response from Target Ovarian Cancer

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Target Ovarian Cancer is the national ovarian cancer charity working to save lives and help women diagnosed live their lives to the full, wherever they are in the UK. We do this by improving early diagnosis, finding new treatments and providing support for women.

Do you agree that NHS England should set a budget impact threshold to signal the need to develop special arrangements for the sustainable introduction of cost effective new technologies?

~~Yes~~/No/~~Partially~~

This presents a significant change in the role of the National Institute for Health and Care Excellence (NICE) in appraising new drugs and treatments.

While we appreciate the cost pressures facing the NHS, and the need to ensure value for money, inserting an additional cost scrutiny process outside of NICE procedures risks undermining the current assessment process to the disadvantage of patients.

While NICE assesses drugs according to their cost per Quality Adjusted Life Year (QALY) this new process would set a cap in terms of absolute treatment costs. It would change the appraisal process from one that strikes a balance between clinical and cost effectiveness, to a blunt tool that potentially risks delaying or denying life-saving and life-extending new treatments.

It is also unclear how this will interact with the interim funding for licensed cancer drug indications introduced by the revised Cancer Drugs Fund (CDF). This funding ends with the publication of final guidance, or at 12 months, whichever is soonest. With the increase in time taken to complete appraisals potentially introduced by the cap, if appraisals pass the 12 month threshold, women with ovarian cancer may face a cat and mouse game where a new drug is available one month but not the next. This creates uncertainty for patients as to which drugs will be available when.

Do you agree that £20 million is an appropriate level? If not, what level do you think the threshold should be set at and why?

~~Yes~~/No/~~Partially~~

Without data published on the annual costs of new drugs approved by NICE it is difficult to estimate whether this is an appropriate threshold or whether it disproportionately affects certain treatments or patient groups.

However, taking the example of olaparib (Lynparza), recently approved for the treatment of ovarian cancer, it is clear how easily a drug could be affected by the new cap. Olaparib has been approved for relapsed BRCA-mutated, platinum sensitive ovarian, fallopian tube or peritoneal cancer in women who have had three or more courses of platinum based chemotherapy. This is currently anticipated to benefit approximately 400 women per year. A single pack of pills covers 28 days and costs £3,550 excluding VAT. Therefore, a year's supply per woman would cost up to £46,150, for 400 women this could be up to £18,460,000 and with VAT that takes it to £22,152,000. (While a patient access scheme has been agreed for olaparib, this only starts after 15 months, at which point the manufacturer picks up the cost of treatment, meaning it would still be subject to the cap even with an access scheme in place.)

(It is not clear whether the £20 million cap would be applied pre or post VAT. As it relates to budgetary impact it can be presumed the cap does include VAT, but if so this further increases the number of new drugs that will be affected.)

While a fixed cap potentially penalises larger patient groups, as the example above shows, it may also include less common cancers. It risks driving perverse behaviours as manufacturers may choose to target increasingly small patient populations with new applications.

Do you agree that NHS England should enter into a dialogue with companies to develop commercial agreements to help manage the budget impact of new technologies recommended by NICE?

N/A

This undermines the role of NICE and ends the current process of evaluating new drugs on the basis of both cost and clinical effectiveness. It would see patients facing delayed access to treatments that had been assessed as having clinical benefit. For patients accessing new drugs under the End of Life criteria this delay could be a matter of life or death. If these proposals are implemented there should be an exemption for those drugs approved for end of life treatment.

Do you agree that if the cost per QALY level is exceeded, the technology should be considered through NHS England's specialised commissioning prioritisation process?

~~Yes~~/No/~~Partially~~

Following reform of the CDF in 2016, cancer drugs to be considered for off-license or off-label use are already referred to specialised commissioning.

As yet there is no information on the process for considering these drugs or how decisions are to be made.

If further new drugs are to be referred down this route then there must be an agreed process for patient engagement, published terms of reference and an appeals and arbitration process. It is important that any drugs considered under this parallel process

are subject to the same public scrutiny and engagement as those considered through the existing NICE process.

While there needs to be a route for drugs not currently suited to the existing NICE appraisal process, this must be transparent and fair.

Do you consider that any proposals in this consultation would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation?

Yes/~~No/Partially~~

Without published information on the annual costs of new drugs approved by NICE it is difficult to predict the different ways equalities duties may be breached.

However, if more expensive drugs such as those for cancer are more likely to be subject to the cap then this risks breaching disability discrimination rules.

Equalities legislation may also be breached in the case of conditions predominantly affecting a large, older patient population, such as new treatments for Alzheimer's.