Paper NHSE111408

BOARD PAPER - NHS ENGLAND

Title: Operation of the Cancer Drugs Fund 2014/15 and 2015/16
From: Sir Bruce Keogh, National Medical Director, NHS England
Purpose of paper: • To update the Board on the outcomes of a consultation exercise on the future operation of the Cancer Drugs Fund, and for decision
Actions required by the Board: • To consider comments made during the consultation exercise • To decide whether to adopt the principles for operation for the Cancer Drugs Fund described in this paper, with or without amendment • to delegate finalising and adopting Standard Operating Procedures for the Cancer Drugs Fund to the Chief Executive, after consultation with the Chair.

The Cancer Drugs Fund 2014-16

Context

1. In 2010 the Government decided to establish a separate ring-fenced Cancer Drug Fund specifically for cancer drugs, and tasked NHS England with running it. The Government establishes the ring-fenced budget for the Cancer Drugs Fund within which it operates via the Mandate to NHS England.

2. The Cancer Drugs Fund (CDF) offers a route for funding treatment for cancer patients that is not included in baseline commissioning. More than 55,000 patients have accessed treatment since the fund was established in 2010 and currently about 2000 new patients per month are starting treatment with a CDF drug. Of the applications made for fast track approval by the CDF, 63% are for drugs which have not been approved by NICE, 22% are in the NICE appraisal process but have not received final guidance and 15% are for drugs used to treat rare cancers for which there is no NICE guidance. The CDF is managed by a panel of expert clinical chemotherapy specialists and patient group representatives.

3. Demand on the CDF continues to grow as new drugs and new indications for treatment develop. In addition, new treatments are coming to market which it is likely the CDF would wish to support. In August this year, NHS England pledged an additional £160 million over two years to strengthen the fund. Even so, if the CDF continues to operate as at present a substantial overspend is projected.

4. As the CDF provides an alternative potential funding source for drugs that are not approved by NICE and currently has to accept the price offered to it, a consequence of the CDF has been to reduce the incentive for some pharmaceutical companies to gain NICE approval by reducing the drug price as part of its NICE submission. This increases budget pressure on the CDF.

5. Therefore the national CDF panel has proposed to review the drugs currently on the CDF list, to ensure that only those demonstrating the greatest degree of clinical benefit, at appropriate costs, remain on the list. This re-evaluation of existing drugs would assess the clinical benefit delivered in treating a patient with a drug, in relation to the cost of that drug. The intention is to remove drugs of lesser benefit from the list and also potentially those more effective but very costly drugs. For this latter group of drugs, the manufacturer has an option to reduce the price and thereby retain funding by the CDF.

6. It is important to be clear that certain principles are absolutely key and are outlined in paragraph 15 and paragraph 27 of this report.

7. The concept of re-evaluating the CDF list is not new. A re-evaluation process is described in NHS England's current Standard Operating

Procedure (SOP) for the CDF. Assessing clinical benefit in relation to drug costs as part of that re-evaluation is new.

8. A four week public consultation was carried out between 3 October 2014 and 31 October 2014. A paper giving information on the CDF and outlining the context in which it is currently working and a draft Standard Operating procedure (SOP) were published for comment. 189 replies were received in total. The attached consultation report at Annex A includes details of the number of responses by stakeholder type and response to each consultation question by stakeholder type. The original text of replies is available to the Board on request.

9. The CDF continues to project a spend in excess of the increased budget of £280m pa for 2014-15 and 2015-16. The reasons include rising patient numbers, rising costs for some new drugs, and new drugs and indications coming in to the fund. The CDF panel considers that being able to accommodate new and better drugs and indications is important both to promote innovation and to ensure that patients continue to have access to better class leading drugs. Some costs fall out of the fund, for example if a treatment becomes recommended by NICE and so passes into baseline commissioning, but the net effect remains that spend in the fund is increasing over time. There is a range of possible responses to this challenge. The first is to do nothing. The effect would be that overspend in the CDF was uncontrolled and would have to be met with reductions in the budgets for NHS clinical programmes, both in and outside cancer. This would be undesirable from a patient equity point of view and would make the management of the other budgets at risk extremely difficult.

10. A second response could be to cease to fund treatments from the CDF once the CDF budget was exhausted. The effect of this would be an arbitrary rationing of treatment by reference to the date on which a patient applied to the fund. Such a system would be inequitable and result in access to treatment for some patients being denied wholly on non-clinical factors.

11. The third response, which is proposed by the CDF panel, is to reduce the products and indications within the CDF to bring the projected spend within budget. This has the advantage that overall spending within and outside the CDF can be managed within budgets, and that spending within the CDF can be allocated on relevant and equitable criteria.

12. Reducing the products and indications within the CDF could be done in a number of ways. The first is to maintain a focus on clinical criteria, but to make clinical criteria for admission to the fund more restrictive. The CDF has never been open to every product which has an indication for use in cancer. There has always been an assessment of clinical benefit. If the threshold used in that assessment was increased, and existing and new products and indications were evaluated against that new threshold, some products and indications would fall outside the CDF with an associated cost saving. However the CDF panel considers that this measure alone

would not be sufficient to bring the CDF within budget, or to enable the CDF to include new products and indications. While the CDF panel recommends that a re-evaluation of the clinical criteria is part of the solution to managing the CDF within budget, additional steps are needed.

13. The CDF panel has proposed an alternative approach which would be to introduce a price criterion alongside existing clinical criteria. This is a new consideration in the operation of the CDF, but it would seem to have the advantage that it is directly relevant to the challenge of operating the CDF within budget.

The proposal

14. The recommended approach from the national CDF panel and the approach which has been subject to consultation is both to re-evaluate the threshold of clinical benefit that is applied, and also to introduce a price criterion. Relying on one or the other of these approaches alone to deliver sufficient savings is not satisfactory, because the threshold that would have to be applied might be so high as to be difficult to justify. Further, continuing to take no account of price in the context of a need to manage the fund within budget seems to overlook a relevant issue. By using both clinical benefit and price to bring the fund back into financial balance we take account of all relevant considerations, can set each criterion at a more moderate level, and can have greater confidence that NHS funds are being spent on products/indications that deliver more clinical benefit per unit cost. This would support NHS England's obligation to act effectively efficiently and economically.

15. It is proposed that the operation of the CDF should remain clinician led and substantially the same as has applied to date. A draft SOP contains the proposals in detail and was published on the NHS England website. The Board's attention is drawn in particular to the following points:

    a. The cost measure taken into account is the median drug cost per patient. A score will be assigned to that cost, and combined with scoring for clinical benefit this will give an overall score for the product/indication. The relationship between cost and score, and the overall scores, will be confidential. This is to protect a manufacturer's commercially sensitive information. (NHS England understands the importance of transparency where that is reasonably possible. However current pricing arrangements are often confidential and we are not introducing a new principle. NHS England believes it must honour that confidentiality for existing products. It does not think it would be fair or encourage innovation to require new products to be priced openly when competitors already on the market still enjoy confidentiality. Further the likely effect would be that fewer if any discounts would be offered, which would not be in accordance with the duty to act effectively efficiently and economically.)

b. The minimum overall score required for approval will be set by the National CDF panel from time to time. The threshold may be adjusted up or down by that panel to ensure that spend within the CDF is kept within budget.

c. Decisions as to which products/indications meet or pass the threshold will be taken by the NCDF, as will decisions on whether and when to conduct a general reprioritisation.

d. The intended effect of the SOP and the planned reprioritisation is that some products/indications that have previously been funded from within the CDF will no longer be funded.

16. The Board is specifically asked to note and agree that there are delegations of authority contained or implied within the SOP regarding the national clinical CDF panel managing within the CDF budget.

17. Transitional and saving arrangements are proposed. No patient whose treatment was already being funded through the CDF would have that funding removed until they and their NHS clinician agreed it should stop. A two month notice period would be given for the removal of any drug/indication. Furthermore, no drug which was the only systemic therapy for the indication in question would be removed. In addition, Individual Funding Requests on the basis of exceptionality are still possible for drugs and indications that are removed from the CDF.

Consultation responses

18. 189 consultation responses were received. A consultation summary report is attached as Annex A.

19. A wide range of responses were received. The findings infer a general agreement that action is required in the short term to address immediate issues of sustainability relating to the CDF and good levels of support for a number of the proposals. It is fair to say that there were also significant voices raised in opposition, and differences of position between different interested stakeholders. There were also many detailed comments and questions raised regarding the proposal.

20. There was a significant view that a more fundamental issue relating to the overall process of appraising, funding and sustaining routine access to new cancer medicines through the NHS needs addressing. Many respondents expressed disappointment that these wider issues were not mentioned within this consultation and that the proposed changes to the operation of the CDF were not linked to longer term solutions to these issues.

21. Responses from pharmaceutical companies were, generally, less positive about the proposals than other groups. Many stated that they could only

support aspects of these proposals if they were implemented alongside evolution to the NICE appraisal process allowing CDF medicines to undergo rapid review through a new NICE value assessment process.

22. In relation to health inequalities, some respondents raised the risk that rare cancers could be disadvantaged through the process due to both a more limited evidence base and higher costs associated with drug development. The CDF panel can reassure the Board that the present prioritisation arrangements specifically allow consideration of drugs for rare cancers with limited evidence bases and this is reflected in the fact that a substantial proportion of approved CDF indications are for rare cancers.

23. A number of respondents also commented that the CDF in itself resulted in inequality by establishing a separate funding mechanism for cancer medicines. However other than possibly rarer and paediatric cancers, consultees did not consistently identify an adverse effect on health inequality or on equality of opportunity from the proposals. The view of the CDF panel remains that an evidence based re-evaluation taking account of cost as well as benefit is expected to be more equitable and better promote access to treatment, although the Board may wish to consider whether and how it could be assured that there have been no adverse effects on equality.

24. Balancing transparency and commercial confidentiality was a very significant theme from the feedback, with many respondents questioning the proposed balance in the draft SOP. In order to protect current and potential future pricing arrangements between pharmaceutical companies and NHS England, which may differ from the public list price of drugs, the proposed process would treat the scoring bands for assessment of drug cost and the individual scores of drugs as confidential. A significant number of consultees felt that too much weight had been given to confidentiality and too little to transparency as regards the application of significant sums of public money.

25. Both the views of those supporting confidentiality and those arguing for more disclosure have force, and it is possible to defend a range of possible solutions. A number of specific options are available to NHS England relating to which aspects of the scoring process are made public. The key aspects of the scoring process involve: cost bandings, clinical criteria, scores against clinical criteria, scores against cost bandings and overall scores.

26. Consideration could be given to making all of this information public. However, expert advice to NHS England is that this presents a significant risk in that this approach will betray information that is regarded as commercial confidence at present and mean that manufacturers are less likely to offer the CDF discounted prices under such a proposal. NHS England cannot simply release information which it currently holds as confidential. It would be an undesirable outcome for a process intended to enable the CDF to be managed within budget, and to increase the health

benefit from that budget, if discounts were reduced or removed. It is suggested that a degree of confidentiality around pricing is necessary to enable the NHS to receive the best prices for drugs, and that by receiving the best prices for drugs the NHS improves outcomes for more patients overall.

27. Therefore, notwithstanding the proper value consultees and NHS England place on transparency, it is recommended that the approach adopted is broadly that which was outlined in the draft SOP:

- the cost bandings should be confidential between NHS England and pharmaceutical companies (we consider in light of consultation responses that companies in particular need this information to understand in advance how their pricing strategies may affect a drug within the CDF. We understand that the information is also of general interest, but only companies need it to inform their decisions)

- the clinical criteria and resultant clinical scores are published publically on the NHS England website (as they currently are)

- to protect commercial confidence the cost score and resultant overall score is kept as commercial in-confidence

28. It is believed that the most important information to publish is the scoring of drugs against clinical criteria listed within the CDF scoring tool, this information being of more direct use to patients and clinicians. It would be possible as an alternative to publish the overall score, and maintain both the clinical and the cost sub-scores as commercial in confidence. This is not recommended as we feel it is less informative to publish a combined score with no indication of either component. In addition it would be difficult to apply this approach to drugs already in the CDF, where a clinical score is already published. By publishing a combined score it is likely that the price score of the product could be accurately estimated.

29. The proposed approach should ensure that there is an opportunity for discounted prices to be offered to the CDF and therefore is in accordance with NHS England duty to act effectively, efficiently and economically.

30. Many detailed comments and suggestions were made regarding how transparency of the process could be improved. These will also be considered by NHS England if the Board approves the principles of the CDF contained in this paper.

31. Timing: Company consultees suggested that significantly more time would be needed to prepare evidence submissions than the SOP would allow. However any delay to re-evaluation necessarily has an adverse impact on the CDF budget. It is not anticipated that companies would be required to provide substantial new evidence. The CDF already has clinical data and a clinical score for treatments within the CDF. In some cases there may be new data to update the score already given, but it is not thought that

major de novo submissions will be required. Unit price is an existing datum, and while there is some scope for evidence around translating unit price to median price per patient this is also not thought to be likely to require substantial evidence. Additionally companies suggested that they may need more time to consider any adjustments they may wish to make to their prices. As it is now proposed to provide companies with price bands in advance of re-evaluation, they will be able to anticipate the likely score for their products and consider adjustments in advance.

32. Nature of the process: Some consultees expressed concern that the process must not amount to price setting, and/or trespass on the role of NICE.

Recommendation

33. The Board is asked to consider the proposals above and the consultation document, and to approve the operation of the CDF in accordance with the principles outlined in this paper, with any further amendments the Board thinks fit, or otherwise give directions as to the future management of the CDF. The Board is asked particularly to have in mind the need to reduce health inequality and to promote equality of opportunity.

34. The Board is asked to consider the consultation report and in particular the issue of balancing transparency with confidentiality and the proposed approach to this issue.

35. The Board is asked to delegate authority to the chief executive, acting after consultation with the chair to adopt a SOP substantially in the form consulted on and additionally to make further amendments to the SOP from time to time that he may think necessary or desirable in particular in the light of experience gained in its operation, The Board is specifically asked to note and agree that there are delegations of authority contained or implied within the SOP regarding the national clinical CDF panel managing within the CDF budget and otherwise.

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