NICE technology appraisals and the Cancer Drugs Fund

Frequently Asked Questions for patient groups

These FAQs are for patient groups who are interested in participating in NICE's appraisals of drugs which are, or could be, in the Cancer Drugs Fund (CDF).

For information about the CDF, please see the NHS England website.

1. **What is the CDF?**
   The CDF historically helped people in England access cancer drugs that were not routinely available on the NHS.

   From 29 July 2016, a new way of appraising and funding all cancer drugs came into force. The CDF has become a managed access fund that provides patients with faster access to the most promising new cancer treatments. This means that if NICE decides that a drug looks promising and potentially cost effective but there is not yet the evidence to recommend it for routine commissioning, the drug will be available through the CDF while further data is collected. Once the data has been collected, NICE will then be able to decide if the drug can be recommended for routine commissioning.

   The CDF will also enable access to treatments earlier in the NICE appraisal process – this may be as much as 8 months sooner than before. Interim funding will be made available as soon as NICE makes a positive draft recommendation instead of when final guidance is published (see NHS England's news article).

   Most new cancer drugs will go through the NICE Technology Appraisal (TA) process to determine whether they can be funded via the NHS.

2. **What is the rapid reconsideration review?**
   The rapid reconsideration review is for cancer drugs that have previously been reviewed through the TA process and were not recommended by NICE, but became available to patients in the NHS through the CDF. These treatments will now go through a rapid review to decide whether they can continue to be available on the NHS.
   The company cannot submit new clinical evidence. The focus is on cost effectiveness analyses of the drug due to the availability of a new patient access scheme or commercial access agreement - a proposal from a company that reduces the cost of a drug to the NHS.

3. **How long is the rapid reconsideration review?**
   The rapid reconsideration review will take 20 weeks. This is 10 weeks shorter than a usual review. The process is shorter because no new clinical evidence is being assessed.

4. **Will people already receiving a treatment via the CDF still receive it?**
   If you are on a drug that is funded through the CDF, you will continue to have access to it until you and your clinician thinks it is appropriate to stop.

5. **How many drugs are going through the rapid review and what are they?**
   Rapid reconsideration process -
   For more information about each transition group visit the NICE website CDF page

6. **Who will be on the committee?**
   Rapid reconsideration review - The committee will be made up of up to 24 individuals who currently sit on the existing TA committees. The names of the members who attended are in the minutes of the appraisal committee meeting, which are posted on the NICE website. The Chair will alternate between the current TA Chairs and so too will the lay members. There will be 2 lay members attending each committee meeting, topic specific clinical and patient experts, the company and the educational research group.

   CDF technology appraisal –The committee will vary between the existing 4 TA committees. Each committee will have 2 lay members, along with topic specific clinical and patient experts, company representatives and leads from the educational research group.

7. **Where will the committee meetings be held?**
   Rapid reconsideration review - The rapid review meetings will be held at the NICE office in Manchester.

   CDF technology appraisal – These will vary between the London and the NICE office in Manchester. This is dependent upon the committee appraising the technology.

8. **How can patient organisations be involved?**
   Rapid reconsideration review – There will not be a consultation on the scope because NICE will be using the same one that was initially reviewed and used when the technology was first appraised.
   Patient organisations will be invited to
   - nominate patient experts to attend the committee meetings.
   - submit a comment on the technology prior to the committee meeting. This will be using the same template that you may have previously used for NICE technology appraisals.
   - comment on the ACD and FAD.

   CDF technology appraisal – patient organisations will be invited to comment on the scope and where relevant invited to attend scoping workshops.
   Patient organisations will be invited to
   - nominate patient experts to attend the committee meetings.
   - submit a comment on the technology prior to the committee meeting using the TA patient submission template.
   - comment on the ACD and FAD.

9. **Will there be patient experts?**
   Rapid reconsideration review – Yes.
   We encourage patient organisations to nominate the same patient experts that they nominated when the technology first went through the TA process. This is because the patient expert will already be knowledgeable of the drug and NICE process. If the same patient expert is not available then we encourage patient organisations to

nominate a colleague who has sound knowledge of the technology and broad understanding of the condition, or a patient who has the condition and has been on the technology.

CDF technology appraisal – Yes.
Nominations will be in the same way that they are for TAs – patient organisations are encouraged to nominate patients with the condition and where possible have been on the technology, and a somebody from the nominating organisation who has sound knowledge of the technology and broad understanding of the condition.

10. **Will meetings be held in public?**
    Rapid reconsideration review - members of the public will be able to register to observe via the NICE website.

    CDF technology appraisal – No. The first meeting will be held in private if it is before Committee for Human Medicinal Products (CHMP) and marketing authorisation.

11. **Will new evidence be accepted during the re-appraisal process, where this is relevant to a drug's re-assessment? If not, why not?**
    Rapid reconsideration review – The company evidence submission should focus on cost effectiveness analyses using the new cost of the drug (the availability of a patient access scheme or as a commercial access agreement). For its cost-effectiveness modelling, the company should use the assumptions that the committee said were most plausible in the existing published guidance. Only in exceptional circumstances, and with prior agreement with NICE, should new the company include new clinical evidence. Submission of new clinical evidence must not lead to substantial changes in the approach to cost effectiveness.

    If the a drug is recommended for use within the CDF rather than routine commissioning new evidence will be collected, normally for a period up to 24 months. These drugs will then be reviewed by NICE at the end of the data collection period.

    Patient groups are invited to submit evidence using the Single Technology Appraisal patient submission template.

12. **Will a drug recommended for use on the CDF, be available to patients throughout its time on the Fund, or will there be a recruitment of patients and then a follow up period (when no new patients are recruited), similar to the way in which clinical trials are conducted?**
    A drug will be available to patients in the NHS throughout its time on the Fund.

13. **Will all patients, who can benefit from a drug's indication, have access to the drugs on the new CDF?**
    Access will be in line with the committee's recommendation.

    The following 3 will options will apply:
    1. Recommended for routine commissioning (either for all patients within the marketing authorisation or for a sub-population of the marketing authorisation)
    2. Recommended within the CDF (whilst data is gathered for a future appraisal)
    3. Not recommended

14. **Will there be a time gap between a drug coming to the end of its time on the CDF and the final appraisal decision for routine commissioning or will it be done straight away?**
    It is planned that the CDF funding for a particular drug will finish when the review of guidance is published. If it is recommended, routine commissioning will begin at that point.

We would like to thank Cancer 52 and Patients Involved in NICE for their help developing these FAQs. We aim to update this document regularly. If you have additional questions to add please email: chloe.kastoryano@nice.org.uk .