

NHS England Commercial Framework Consultation Response (January 2020)

Introduction and summary (not submitted in online consultation)

Cancer Research UK is the world's largest charitable funder of cancer research, improving the prevention, diagnosis and treatment of cancer. In 2018/19 we committed £546 million to research into all 200 types of cancer. Thanks to research, survival in the UK has doubled since the 1970s so, today, 2 in 4 people survive their cancer. Our ambition is to accelerate progress and see 3 in 4 patients surviving their cancer by 2034.

All cancer patients should have access to the best, evidence-based treatments for their condition. NHS England's commercial activity and ability to negotiate with pharmaceutical companies has been a critical enabler of improved patient access to new cancer medicines in recent years, ensuring patients get access to the medicines they need, whilst paying a fair and sustainable price.

The Framework provides welcome clarity and transparency on NHS England's commercial policies and processes. It represents a crucial step forward in facilitating valuable discussion among all key stakeholders, including patients and the public, about how prices for new medicines are agreed.

However, it is crucial that legitimate concerns to control budget impact and manage administrative burden are not put ahead of a willingness to consider commercial flexibility where this could support faster or more comprehensive patient access. The commercial approach the Framework sets out (with a preference for simple percentage discounts, unless products are considered highly cost-effective) has delivered real benefits to the NHS and for people affected by cancer in recent years, but it does not do enough to anticipate and respond to trends which are now emerging in the regulatory and drug development landscape.

Complex flexible agreements (like outcome-based payment) may not be appropriate for every new medicine, but there will be instances where such agreements would be beneficial. We are concerned that the policies and processes the Framework outlines may hinder early and proactive discussions between NHS England and companies where a more flexible approach could better maintain and enhance patient access to new cancer medicines.

1) Please tell us which organisation you work for/are responding on behalf of

Cancer Research UK

2a) Are the objectives and principles underpinning the Commercial Framework for Medicines clear?

Yes

2b) Is anything missing?

The Framework does not explicitly define promoting patient access to new medicines as a core objective or principle of NHS England's commercial medicines activity. Promoting patient access to new medicines should be an objective of the Framework, and of the commercial activity it will guide, in and of itself.

It is crucial that the processes and commercial models outlined in the Framework are active enablers of patient access to clinically and cost effective new medicines. While the three core objectives outlined in Paragraph 11 all represent welcome commitments, the Framework should be clear that meeting these objectives as part of NHS England's commercial activity only represents a means towards the primary goal of promoting patient access to new medicines. This would be in line with the ambition outlined in Section 1 (Aims & Purpose) of the Framework, to "deliver patient access to proven, affordable and transformative medicines in a financially sustainable way".

3a) Are the respective roles and responsibilities and the processes for engaging with NICE and NHS England clear?

Yes. We welcome the transparency the Framework provides about the roles of NICE and NHS England in the appraisal and reimbursement process for new medicines, and the delineation of these bodies' respective responsibilities. This clarity could help avoid delays in the path to reimbursement for new medicines – thereby accelerating patient access – as well as providing welcome transparency into the process for patient groups and other interested parties.

The desire for transparency about how NHS England, NICE and other parts of the NHS collaborate in agreeing the price for new medicines with companies was a key theme raised by people affected by cancer we consulted to inform this response, and NHS England should consider how to effectively communicate and promote this information to a wider patient and public audience.

3b) Where would further clarity be helpful?

The Framework could be clearer on the activity NHS England and NICE intend to undertake proactively to deliver horizon scanning and early engagement with companies. This will help to maximise the chance that issues (such as substantial uncertainty in a product's clinical effectiveness in the long-term or for a particular sub-group of patients) which could complicate commercial negotiations are resolved at an early stage, preventing subsequent delays to patient access.

The options outlined in Figure 2 are descriptive of the support NHS England can offer through Commercial or Clinical Surgeries, and that NICE can offer through its Office for Market Access and Scientific Advice service. However, the Framework does not specify whether this activity could or should be initiated by NHS England or NICE, or if it is solely available at companies' request.

NHS England should be clear that it will work with NICE to identify products where this early engagement could benefit all parties (especially patients, through delivering faster access to new treatments), and that it will encourage companies to work with NHS England and NICE to achieve this. The Framework should in turn clarify how this ambition will be achieved.

4) Are the routes to commissioning and funding new treatments within the NHS clear?

Yes

5a) Is the framework of commercial options available clear?

In Figure 6 and the following paragraphs of Section 5 (Commercial Options), it is not clear why commercial options to address affordability challenges related to the Budget Impact Test have been listed as a separate category of commercial option in themselves. Commercial activity to resolve affordability challenges under the Budget Impact Test does not appear to meet different objectives or involve additional steps to other processes and options outlined in Section 5.

Commercial agreements to address affordability challenges related to the Budget Impact Test would appear simply to represent a special case of the more general ambition and purpose of such agreements, outlined as a “central issue” in Paragraph 12 of the Framework, of “ensuring the introduction of clinically and cost-effective treatments are affordable for the NHS”. Moreover, the agreements to achieve this ambition would presumably take the form of a Patient Access Scheme (PAS), Confidential Commercial Arrangement (CCA), or Commercial Access Agreement (CAA) as part of a Managed Access Agreement (MAA).

5b) Where would further clarity be helpful?

As per the answer above, if there is any systematic difference between the commercial process for medicines where the Budget impact Test has been triggered and medicines where the Test has not been triggered, the Framework should clarify this. Likewise, if there is any systematic difference between commercial agreements reached through discussions necessitated by the Budget Impact Test and any of a PAS, CCA or CAA as part of a MAA, the Framework should clarify this. This will help avoid confusion about the process of securing commercial agreement, and ultimately patient access, where the Test is triggered.

6) What is missing from the commercial framework?

The Framework should do more to anticipate and articulate how NHS England’s commercial medicines activity will be future-proofed, and the need for complex commercial agreements to make up a greater share of NHS England’s commercial medicines activity in future.

We are disappointed that commercial flexibility is expected to be reserved for products which can demonstrate cost effectiveness at or below the lower end of the standard NICE cost effectiveness threshold. Instead, we see commercial flexibility (such as the use of complex CCAs like outcome-based payment schemes) as an important tool for the NHS to manage increasing systemic uncertainty in the cost effectiveness of new medicines, and to continue to promote patient access to new innovative medicines against this backdrop.

Cancer Research UK’s work into the use of outcome-based payment for cancer drugs in the NHS has found a number of trends in the regulatory and drug development space driving increased uncertainty in the clinical and cost effectiveness of new medicines at the point where the NHS has to decide whether to fund their use, and at what price. These trends include:

- the increasing cost and innovative nature of many new treatment options;
- increasing awareness of the demographic and outcomes gap between clinical trial and NHS patient populations; and
- the licensing of new medicines based on less mature or less complete clinical trial data (often from fewer trial patients than in the past).

NHS England’s successful use of the simple PAS model to drive fair and affordable prices for new medicines has been a key contributor to increasing access to new medicines for many cancer patient populations in recent years. We wish to see this continue where possible, and we agree that a simple PAS should remain NHS England’s preferred commercial option and the starting point for commercial negotiation.

However, the trends noted above, and the uncertainty they imply, will require different approaches to be taken in an increasing number of cases in future, in order to safeguard continued patient access to future innovative cancer medicines. While complex flexible agreements will not be appropriate for every new medicine, we are concerned that the requirement for simple discounts to be “fully demonstrated to be unsuitable” (as set out in Principle 3 of the Framework) before more complex arrangements can even be considered may hinder early and proactive discussions between NHS England and companies on complex CCAs (like outcome-based payment) for suitable medicines, and so delay patient access to future innovative medicines.

Our research into the use of outcome-based payment for cancer drugs in the NHS concluded that the use of complex commercial arrangements like outcome-based payment can help accelerate patient access to new medicines in cases where there remains uncertainty about a treatment’s clinical and cost effectiveness, even once mature clinical trial data are available. NICE’s November 2019 Appraisal Consultation Document for the CDF Review of TA519 (pembrolizumab for locally advanced or metastatic urothelial carcinoma previously treated with platinum-containing chemotherapy), where NICE noted substantial uncertainty remained about the drug’s long-term benefits for a substantial minority of patients, demonstrates the potential for this scenario to arise.

We acknowledge the concerns outlined in the Framework around additional burden to frontline staff created by complex agreements. However, a greater focus on collecting real world data on patients’ treatment regimens, outcomes and experience (as is required to operate many of the models outlined in Table 1) will be beneficial for both the NHS and patients. There was a clear consensus from the people affected by cancer we consulted to inform this response, that such data capture should be a priority for the NHS in any case, and that using NHS staff time in this way represents a worthwhile trade-off if it can help manage concerns about cost effectiveness. There was also consensus that companies should be expected to share or offset any additional burden.

The next phase of our research into outcome-based payment is looking into how the NHS’ existing data capabilities can be harnessed to support commercial flexibility, as well as ways to minimise the burden to frontline staff from data collection as part of complex schemes, and we are pleased that representatives from NHS England remain involved in this work.

Separately, Section 1 of the Framework (Aims and Purpose) should clarify that the Framework represents a “living document”. It should be clear that the current drafting of the Framework does not preclude the future evolution of the processes and commercial options it outlines, as required to ensure the Framework remains optimally set up to “promote innovation and access to cost effective medicines”, in line with the ambition outlined in the VPAS.

Finally, the Framework should more explicitly set out how patients’ interests and perspective are represented and considered in the operation of the commercial process. The importance of ensuring the process is geared towards the best possible outcomes for patients was a clear theme raised by people affected by cancer we consulted to inform this response.

While legitimate concerns, including commercial confidentiality, will make direct patient or charity involvement in price discussions impractical and/or inappropriate in most cases, it is crucial patients and the public can be sure those discussions are based on a clear understanding of how a new treatment option could positively impact their care and treatment outcomes. This should include providing greater clarity on how (quantitative or qualitative) data on factors such as quality of life and patient-reported outcome measures is sought and considered in the commercial process.

7) What additional information could be included?

The Framework should include information on the process to update the document, if the processes and commercial models it outlines are judged to no longer be the best-suited to achieving the aims and objectives outlined in the document. Establishing a clear process of this kind will help to ensure any updates can be agreed and implemented quickly, allowing the Framework to support timely patient access to future clinically and cost-effective medicines as effectively as possible.

The Framework should also include information on what procedures will be followed if a company and NHS England are unable to agree a commercial arrangement in a timely manner, and there is a need to escalate commercial discussions beyond the Commercial Medicines Directorate (including any expectation of input from outside 'third parties' such as patient organisations, such as providing additional data or supporting more direct patient input to the process at this stage). A clear procedure to be followed in such cases could help to reduce any delays in securing patient access to medicines which could offer benefits to people affected by cancer (and other conditions).

8) Are you aware of any impact this framework might have on health equalities?

No

To discuss this response further please contact Duncan.Sim@cancer.org.uk