

Classification: Official

Publication approval reference: PAR1686

The Innovative Medicines Fund Principles

6 June 2022

Contents

1. Background and purpose.....	2
2. Introduction to the Innovative Medicines Fund and Managed Access	4
3. Guiding principles for the Innovative Medicines Fund.....	6
4. Key features of the Innovative Medicines Fund	9
(a) Entry into the Innovative Medicines Fund	9
(b) NICE guidance.....	9
(c) Resolving uncertainty through the Innovative Medicines Fund	11
(d) Commercial access agreements.....	14
(e) Exiting the Innovative Medicines Fund and updated NICE guidance.....	16
(f) Interim funding for NICE recommended medicines	18
(g) Financial control.....	19
Appendix 1: Glossary.....	21

1. Background and purpose

1. This document sets out our guidance and policy approach for the Innovative Medicines Fund, which will operate alongside, and on similar terms to, the [Cancer Drugs Fund \(CDF\)](#). Like the CDF, the Innovative Medicines Fund will have a fixed funding envelope of £340 million per annum, creating a total of £680 million of ringfenced NHS England funding for early access to the most promising medicines.
2. Since 2016 the CDF has provided earlier, time-limited access to promising new cancer medicines via managed access agreements (MAAs), while further evidence is collected on their clinical and cost-effectiveness. This has benefitted over 80,000 patients who have been able to access 96 CDF funded medicines treating 218 cancers.
3. This managed access approach has played a key role in responding to a long-standing challenge in the evaluation of cancer medicines, where the data available to NICE is not always sufficient to make long-term decisions regarding the clinical effectiveness and value for money of new medicines or indications.
4. In these situations, the CDF and use of MAAs has meant that NICE can recommend medicines for a limited time while further data is collected to clarify any identified uncertainties. NICE then uses this data to recommend whether or not the medicine should be made routinely available on the NHS.
5. A similar challenge faces non-cancer medicine evaluations, particularly those for rare conditions, where limited data, and with that significant uncertainty, would result in negative NICE guidance. While cancer medicines used to dominate NICE's evaluation programme, today there is a more even split between cancer and non-cancer evaluations. In addition, there is a growing pipeline of promising medicines for rare conditions, which offer the potential to improve outcomes and transform the quality of life for patients and their carers.
6. The creation of the Innovative Medicines Fund will ensure there is equal potential for cancer and non-cancer patients to benefit from the latest medicines.

7. The [Innovative Licensing and Access Pathway \(ILAP\)](#) will help NICE and NHS England identify potential candidates for the Innovative Medicines Fund and provide an opportunity for multi-agency discussions about further data collection requirements.
8. In addition to supporting promising but uncertain medicines, the Innovative Medicines Fund (like the CDF) also presents an opportunity to accelerate the introduction of proven medicines where NICE is able to confidently recommend a medicine for routine use in the NHS.
9. **Section 2** of this document introduces the Innovative Medicines Fund and the key features of managed access. **Section 3** gives the principles underpinning it and **Section 4** outlines the key features of the Innovative Medicines Fund, including detail on how the Innovative Medicines Fund will work in practice.
10. The Innovative Medicines Fund will amplify the impact of the [increased commercial flexibilities](#) that NHS England, working in partnership with NICE, can offer to those companies that are willing to price their products realistically and responsibly.

2. Introduction to the Innovative Medicines Fund and Managed Access

11. The fastest way for a medicine to reach NHS patients is for a company to submit evidence of its clinical-and cost-effectiveness through a NICE health technology evaluation (i.e. technology appraisal or highly specialised technologies).
12. Where NICE finds the case has not been made for routine use in the NHS because it needs further data to resolve the outstanding uncertainty, the Innovative Medicines Fund, as a managed access fund, has the potential to significantly benefit patients by opening the opportunity for them to access promising new medicines whilst this data is collected.
13. The Innovative Medicines Fund will provide a consistent and transparent managed access process for companies offering promising non-cancer medicines at a responsible price.

What is managed access?

14. Managed access is an approach that the NHS takes to ensure patients can access promising but still clinically uncertain medicines, while supplementary data is collected (over a time limited period) to allow more informed decision making about patient access and long-term NHS funding.
15. For any medicine NICE recommends with managed access, a MAA is put in place between NHS England and the company. MAAs consist of two parts:
 - a time-limited Data Collection Agreement (DCA) that outlines the data to be collected that should address the evidential uncertainties (as defined by NICE)
 - a Patient Access Scheme and/or a Commercial Access Agreement (CAA) to ensure that the MAA offers value to taxpayers during the managed access period

16. At the end of the data collection period, the data collected, along with any other available and relevant evidence, is submitted to NICE to make the final recommendation on whether the medicine should be routinely available on the NHS.
17. The [Commercial Framework for New Medicines](#) gives more detail on how NHS England work in partnership with NICE and companies on commercial medicines activity to deliver patient access to proven, affordable and transformative medicines in a financially sustainable way.
18. NICE has recently published the [NICE health technology evaluations: the manual](#) (2022) which describes the methods and processes, including expected timescales, that NICE follows when carrying out health technology evaluations. The Innovative Medicines Fund aligns fully to the NICE Manual.

3. Guiding principles for the Innovative Medicines Fund

19. The design of the Innovative Medicines Fund has been informed by NHS England and NICE's experience from the CDF and other commercial and data collection arrangements and via engagement with industry, patient organisations, clinicians, academics and data custodians.
20. Our experience has reinforced the importance and relevance of the principles underpinning the CDF that should similarly underpin the Innovative Medicines Fund.
21. The principles that will guide the Innovative Medicines Fund are:

Principle 1: The Innovative Medicines Fund should operate as a managed access fund for non-cancer medicines so that any patient, regardless of their condition, has equal potential opportunity to benefit from promising but uncertain medicines. The Innovative Medicines Fund will extend the principles of the CDF so that NICE can recommend any promising medicine, for a limited time, while further data is collected to resolve evidential uncertainty. The increasingly even split between cancer and non-cancer NICE evaluations reinforces the case for extending managed access beyond cancer to address evidential uncertainty.

Principle 2: The Innovative Medicines Fund should target the most promising medicines for which there is significant remaining uncertainty around the level of clinical benefit and cost-effectiveness. Medicines will be suitable if they address a high unmet need; provide significant clinical benefits; represent a step-change in medicine for patients and clinicians; and the new evidence to be generated is considered meaningful and could sufficiently reduce uncertainty.

Principle 3: Recommendations with managed access should be reserved for medicines that (a) demonstrate plausible potential to be cost-effective; and (b) are priced responsibly during the period of managed access, reflecting their uncertain cost effectiveness. To be recommended with managed access, medicines will both need to demonstrate their potential

to be cost-effective, as determined by NICE, and deliver value for money by being priced responsibly, as determined by NHS England. The price should reflect both the uncertainty as well as the overall burden imposed on the NHS by any data collection arrangements. Those medicines that show greatest certainty of clinical benefit and cost-effectiveness should be valued most highly.

Principle 4: Managed access should be for the shortest time necessary to collect the data required to resolve any uncertainties identified by NICE. The purpose of ‘managed access’ is to resolve significant remaining uncertainty associated with a medicine so that NICE can make a recommendation on routine commissioning in the NHS. Managed access does not displace or replace the need for good quality clinical trials. Any data collection arrangement should generate timely, high-quality data and should be limited to the uncertainties that are required to be addressed during the managed access period, recognising that managing these arrangements is highly resource intensive for all parties. The timeframe should be as short as possible to provide certainty to patients and the NHS and to minimise the burden on all parties. The appropriate timeframe will be considered on a case-by-case basis and will not exceed five years.

Principle 5: The entire eligible patient population, as determined by NICE, should have the opportunity to access medicines recommended for the Innovative Medicines Fund in the managed access period.¹ There will be no cap on the number of eligible patients who can access the medicine during the period of managed access.

Principle 6: All medicines that enter the Innovative Medicines Fund must be re-evaluated by NICE, who will make final recommendations on whether the medicine should be routinely available on the NHS. In signing up to a MAA companies must commit to fully engage with a NICE guidance update of their medicine at the end of the data collection period. At this time price adjustments may be made, either upwards or downwards, and NICE will make a final decision on whether the medicine should be routinely available on the NHS.

¹ The duration of an MAA, including both the data collection period and the time required for the NICE guidance update.

Principle 7: Any patient who starts treatment with an Innovative Medicines Fund recommended medicine during the period of managed access should have the option of continuing that medicine in the event that NICE is unable to recommend its routine use in the NHS at the end of the NICE guidance update. If a medicine is not recommended for routine commissioning at NICE guidance update, patients who started on treatment during the period of managed access will continue to receive the medicine until such time that the patient and the treating clinician determines it is no longer clinically appropriate. No further funding will be available for medicines that NICE does not recommend for routine commissioning in the NHS. Any patients who were prescribed the medicine when it was in the Innovative Medicines Fund will continue to receive it at the company's cost.

Principle 8: The Innovative Medicines Fund should never have to close to potential new entrants. The Innovative Medicines Fund will operate within a fixed budget of £340 million with an expenditure control mechanism (ECM) to ensure that any spend above this is paid back on a proportional basis by all companies receiving funding from the Innovative Medicines Fund. Agreeing to the ECM will be a condition for all companies receiving funding from the Innovative Medicines Fund and will ensure that the Innovative Medicines Fund does not have to close to new entrants.

22. The above principles underpin the primary role of the Innovative Medicines Fund: operating as a managed access fund. In addition to this, the **Innovative Medicines Fund could provide a potential source of funding to support earlier access to certain medicines that NICE is able to recommend for routine use in the NHS**. For further details, including how this mirrors arrangements in place for cancer drugs through established CDF 'interim funding' agreements, see paragraphs 66-71.

4. Key features of the Innovative Medicines Fund

23. Since April 2020, NICE has evaluated all new active substances licensed for their first indication and significant new indications, except where there is a clear rationale not to do so. These evaluations follow the standard process described in the [NICE health technology evaluations manual](#) (2022). This document should be read in conjunction with the NICE Manual.

(a) Entry into the Innovative Medicines Fund

24. It is essential that companies engage early so that NICE and the NHS can identify potential candidates for managed access and consider data collection needs and service preparedness as well as opportunities for further evidence generation to be developed. Early engagement activities between NICE, NHS England and companies aim to address potential barriers to patient access and identify, develop and assess the feasibility of opportunities for new prospective data collections, ahead of the NICE evaluation. For the medicine being evaluated, they also provide a chance to identify relevant future comparators in the pipeline.
25. Companies interested in managed access must engage early with NICE and demonstrate that their technology is suitable for the Innovative Medicines Fund having considered the following factors:
- the technology has the potential to address a high unmet need;
 - the technology has the potential to provide significant clinical benefits to patients; or
 - the technology represents a step-change in medicine for patients and clinicians; and
 - the new evidence to be generated is considered meaningful and could sufficiently reduce uncertainty.

(b) NICE guidance

26. The NICE Manual outlines the recommendations NICE can make, including:

- recommended for use
 - recommended with managed access – ‘time limited’ access (via the Innovative Medicines Fund or CDF with a MAA)
 - case is not supported
27. When there is still significant resolvable uncertainty and NICE is not persuaded to make a recommendation for routine use, it can make a recommendation with managed access for further evidence to be gathered subject to a MAA. The committee can consider a recommendation with managed access when:
- the medicine has not been recommended, it has the plausible potential to be cost effective at the currently agreed price, but the evidence is currently too uncertain, and
 - new evidence that could sufficiently support the case for recommendation is expected from ongoing or planned clinical trials, or could be collected from patients having the medicine in clinical practice, and
 - these data could feasibly be collected within a reasonable timeframe (up to a maximum of five years) without undue burden.
28. Medicines that are recommended with managed access through the Innovative Medicines Fund will be made available to all eligible patients under the terms of the MAA. As they are not, at this stage, being recommended for routine use in the NHS patient access is not provided under Section 7 or 8 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.
29. A recommendation with managed access is not considered established practice in the NHS because:
- the committee has found that a recommendation cannot be supported, until further evidence is available
 - the committee has made a recommendation with managed access using a temporary price to mitigate the uncertainty
 - the funding during the evidence generation period for these medicines is made available from dedicated managed access funds, rather than routine NHS funding

- if, once further evidence is available, the committee does not recommend the medicine, the medicine will then not be available in the NHS for people who have not yet had treatment
- although there is plausible potential to satisfy the criteria for a recommendation, the uncertainty in the clinical data (and consequently the cost-effectiveness estimates) was too great to make such a recommendation at the time of the evaluation.

(c) Resolving uncertainty through the Innovative Medicines Fund

30. A recommendation with managed access is intended to reduce uncertainty about specific evidential issues identified by NICE. When considering whether a medicine is a suitable candidate for the Innovative Medicines Fund, NICE will describe the specific area(s) of uncertainty that are preventing it from recommending the medicine for routine commissioning in the NHS, and the data that could feasibly be collected within a reasonable time to sufficiently resolve these uncertainties. Any data collection for managed access must be feasible to undertake, have a credible chance of addressing the uncertainties and avoid adding undue burden for patients and/or clinicians.
31. Data collection requirements will depend on the uncertainties identified. NICE will seek advice from clinicians, patient groups, academics and data custodians to ensure each Data Collection Agreement (DCA) takes account of the considerations from multiple stakeholder perspectives. Depending on the nature of the data collection and required analyses, NICE will work with the company to facilitate the development of an appropriate approach to data collection and analysis, which will be outlined in the DCA.
32. Managed access does not displace or replace the need for good quality clinical trials. Data sources that will be used to collect data that sufficiently resolves the identified uncertainty may be ongoing or planned clinical trials, or from patients having the medicine in clinical practice.
33. NICE and NHS England acknowledge the value of engaging early with stakeholders such as patient groups and clinicians in harnessing expertise and considering the key challenges and issues that might arise. This engagement is vital to ensure the appropriate design, development and oversight of DCAs and is set out in the NICE Manual.

34. Advice from NICE will inform the duration of the DCA. The duration will:
- be considered on a case-by-case basis
 - be as short as necessary to address the identified uncertainties
 - include review points to check progress
 - cover the data collection period² (up to a maximum of five years) plus the time NICE requires to update the guidance.
35. NICE will be responsible for:
- Identifying the uncertainties that are impacting their decision-making
 - facilitating the development of the DCA
 - supporting all stakeholders to understand and to fulfil their roles according to the DCA
 - co-ordinating activity for stakeholders involved in data collection to ensure they are proceeding as planned to generate the additional evidence for the NICE guidance update
 - providing information to all stakeholders about the guidance update process, following a period of managed access in the Innovative Medicines Fund
 - updating the guidance following a period of managed access in the Innovative Medicines Fund.
36. Companies will be responsible for:
- paying the costs of data collection, validation and analysis
 - commissioning the development of a data/statistical analysis plan to ensure methods and analytical outputs are clearly outlined and agreed within six months of the start of the MAA
 - keeping NICE informed of any anticipated changes to the time required for data collection
 - engaging fully with the NICE guidance update at the end of the data collection period
 - covering the continuing treatment costs for any patients benefitting from the medicine who were prescribed the medicine when it was in Innovative

² The time specified in the DCA for data collection and analytical outputs to be developed.

Medicines Fund if NICE finds that the case has not been made to recommend routine use in the NHS at the point of NICE guidance update.

37. NHS England will be responsible for:

- operating the fund
- commissioning treatments via the Innovative Medicines Fund
- facilitating real world data collection by NHS providers
- making submissions during the NICE evaluation process
- highlighting potential criteria for patient eligibility, and;
- jointly (with NICE) assessing the burden on clinicians, patients and the service to ensure each MAA is a proportionate response to the resolvable uncertainties.

Ongoing clinical trials may be the primary source of data, where they are collecting data that could address the uncertainties identified. Data collected in clinical practice may be collected alongside an ongoing clinical trial to supplement trial data or to address specific identified uncertainties.

38. The DCA will be reviewed and incorporated into the MAA once approved.

39. While a medicine is in the Innovative Medicines Fund, data will be collected as per the DCA.

40. Five years is the maximum duration of the data collection period for managed access in the Innovative Medicines Fund. It has been established as a proportionate period to allow evidence from ongoing clinical trials and real world data collection to mature whilst the NHS pays for an uncertain treatment. The managed access period should be completed in the shortest time possible to reduce burden on patients, their carers and the NHS.

41. The DCA will include a requirement for the company to make a new evidence submission to NICE at the end of the data collection period. The duration of the MAA will allow sufficient time to complete a NICE guidance update using the new data and any other evidence that is available. The NICE process and methods in place when the company is invited to participate in the guidance update will be used.

42. NICE will co-ordinate arrangements, through a Managed Access Oversight Group, to maintain a regular overview of each DCA with stakeholders. The Oversight Group will have representation from NHS England, data custodians, the company, clinicians and patient groups (as required). Arrangements may include an interim review of a DCA at a prescribed time point to confirm that the data collection is on track and delivering the analytical outputs required for the NICE guidance update. Several systems in the NHS will support this process, e.g. electronic prescribing and NHS England's High Cost and Cancer Drug Prior Approval System (Blueteq™). These processes are described more fully in the [NICE Manual](#).
43. Key to the success of managed access agreements is effective data collection and subsequent analysis to address identified uncertainties. Therefore, NHS England will ensure that all NHS providers responsible for submitting data are able to do so.

(d) Commercial access agreements

44. A recommendation with managed access via the Innovative Medicines Fund will trigger the need for a commercial conversation with NHS England to agree a commercial access agreement (CAA) (although, ideally, commercial conversations will have already begun). The CAA will form part of the MAA and determine the level of reimbursement to manage the cost of a medicine to the NHS in a sustainable and financially sound way during the managed access period. This will be a confidential agreement between NHS England and the company.
45. The Innovative Medicines Fund CAA will determine the level of reimbursement during the managed access period. This will be a confidential agreement between NHS England and the company, with input from NICE, and will be considered on a case-by-case basis. The level of reimbursement within the CAA reflects the decision uncertainty, and, as a minimum, the company will need to present an offer that brings the range of plausible cost effectiveness estimates as determined by NICE to below the relevant cost effectiveness threshold (i.e. £20k-£30k per QALY for a technology appraisal or £100k per QALY for a highly specialised technology, taking account of any applicable QALY weightings). Greater commercial flexibilities will be reserved for products that offer greater value and potential health gain to the health service.

46. Each CAA will be considered on a case-by-case basis, to support the inclusion of medicines in the Innovative Medicines Fund and facilitate patient access and is subject to the company and NHS England agreeing a CAA that ensures the medicine provides value to taxpayers during the managed access period.
47. A NICE recommendation for managed access use in the Innovative Medicines Fund is a conditional recommendation, and patient access to the medicine is therefore funded by the Innovative Medicines Fund. The NICE guidance update will provide a final recommendation concerning the future use of the medicine in the NHS, and this may not be routine use. Each MAA will include safeguards to ensure any eligible patients who have started an Innovative Medicines Fund recommended medicine have the option to continue that medicine in the event that NICE does not recommend it for routine use in the NHS.
48. Each MAA, must have both components (the CAA and DCA) agreed to and signed by the relevant parties prior to publication of the draft final guidance by NICE.
49. All eligible patients will have access to medicines NICE recommends for managed access use in the Innovative Medicines Fund.
50. If the company does not propose an acceptable CAA within the timelines set out in the [NICE Manual](#), the medicine will not enter the Innovative Medicines Fund and not be available to patients. In that situation, NICE will be making a recommendation that the medicine should not be routinely commissioned in the NHS because the case for adoption is not supported. If the company offers a new reimbursement proposal after the Draft Final Guidance is published, NICE may reconsider the medicine as part of a new evaluation, subject to NICE charging associated with a new evaluation.
51. To be approved any CAA must be operationally manageable for the NHS, without unduly complex monitoring, disproportionate additional costs and bureaucracy, and it must allow the ECM to be applied fairly. Any burden for the NHS should be proportionate to the benefits of the managed access approach taken in the Innovative Medicines Fund for the NHS and patients.

52. A Budget Impact Test (BIT) assessment will not apply to any part of a patient population for a medicine recommended with managed access use in the Innovative Medicines Fund but will be applied at the point of NICE guidance update.

(e) Exiting the Innovative Medicines Fund and updated NICE guidance

53. All medicines recommended with managed access in the Innovative Medicines Fund will be subject to a NICE guidance update at the end of the data collection period. The guidance update will be undertaken according to the NICE process and methods in place at the time of the invitation to participate, and will be subject to the associated NICE charges.
54. The company must fully engage with a NICE guidance update and provide a further evidence submission, including an updated proposed price, to support a NICE guidance update following a period of managed access. The company must fully engage with a NICE guidance update as detailed in the NICE manual. If a company fails to do this, NICE will withdraw the guidance.
55. A medicine will begin the process of exiting the Innovative Medicines Fund at the end of the data collection period specified in the DCA or the time limit of a maximum of five years data collection is reached, whichever is sooner. NICE will schedule the guidance update to coincide with the end of the data collection period. Patients will continue to have access to the medicine and new patients may start on this while the NICE guidance update is ongoing.
56. NICE and NHS England will have a single process for MAA exits, one which will take account of changes in clinical pathways, new evidence and commercial options following a period of managed access. The NICE guidance update will look at all the available evidence afresh: it will not continue the original evaluation, rather reconsider the case for adoption. The NICE guidance update will consider all relevant evidence – including any evidence submitted during the original evaluation, new evidence that has become available and the new data collected, along with a new price proposal from the company. At this time price adjustments to the medicine may be made, either upwards or downwards, and NICE will make a final recommendation for routine use in the NHS, or not.

57. If, following a NICE guidance update, NICE recommends a medicine for routine use in the NHS, the medicine may benefit from Innovative Medicines Fund funding from the time the positive draft recommendation (which is subject to the ECM) is published, at the price that generated the recommendation (see paragraphs 59-64).
58. If, following a NICE guidance update, an Innovative Medicines Fund medicine is:
- a. **Recommended:** it will transfer to routine commissioning within 90 days of final guidance publication (or within 30 days for medicines with an Early Access to Medicines Scheme [EAMS] designation).
 - b. **Recommended in specific circumstances (i.e. optimised):** it will transfer to routine use for the eligible patient population, within 90 days of final guidance publication (or within 30 days for medicines with EAMS designation). For the patient population not covered by the NICE recommendation, see paragraph c (below)
 - c. **Not recommended for use:** no further funding will be available for new patients to be prescribed the medicine from the date of final guidance publication, because it has not been recommended as a clinical and cost-effective medicine for the NHS to use. Any patients who have been prescribed the medicine during the time the medicine was in the Innovative Medicines Fund will continue to receive the medicine at the company's cost until the patient and the treating clinician deems it appropriate to discontinue treatment and/or they meet a medicine stopping criteria (in line with NHS treatment continuation policies or company-sponsored free of charge schemes).
59. The MAA will clearly define the exit strategy, balance risks and take account of NHS treatment continuation policies, to give clarity to clinicians, patients and their carers, commissioners and the company should NICE not recommend any medicine for routine use following NICE guidance update.
60. It is possible, when exiting the Innovative Medicines Fund, for the cost of the product to increase or decrease, depending on the NICE evaluation of cost-effectiveness at the point of guidance update.

61. The final price will apply to both existing and new patients from the point of the guidance update. The NHS in England will continue to adopt uniform pricing by medicine; it does not operate blended pricing or pricing by indication.
62. A medicine that NICE recommends for routine use in the NHS, following a period of managed access, will be subject to a BIT assessment as per the [NICE Manual](#) before it can be routinely used in the NHS.
63. A condition of entry into a MAA is that the company will be required to engage fully with the NICE evaluation process and methods.
64. Even if a company withdraws from the MAA or decides not to proceed with the NICE guidance update, it will be required to participate in an engagement event with all stakeholders and provide information about the reasons for not proceeding with the guidance update, including information about the available evidence. The outcome of this process will be published on the NICE website.
65. In signing up to a MAA, all companies are accepting that at the end of the data collection period, NICE will update the guidance for the medicine, using the methods and process that are in place at the time they were invited to participate in the guidance update. NICE will make a final recommendation for routine use in the NHS, or not. There will be no opportunity for NICE to make a further recommendation with managed access in the Innovative Medicines Fund.

(f) Interim funding for NICE recommended medicines

66. The primary function of the Innovative Medicines Fund is to operate as a managed access fund while evidential uncertainty is resolved in medicines that otherwise show significant clinical promise. In addition, the Innovative Medicines Fund could provide a discretionary source of early funding for certain medicines that NICE can recommend for routine commissioning in the NHS from the point of marketing authorisation. Legislation requires the funding of NICE approved medicines within 90 days of final guidance being published. However, under these arrangements, funding could be brought forward by up to five months, starting at the point NICE issues a draft positive final guidance.

67. To benefit from 'interim funding' companies will need to have priced their products responsibly to obtain a routine commissioning recommendation from NICE, received a marketing authorisation and provided complete, accurate and timely information to support service planning.
68. For some medicines the NHS will need more time to support pathway change from a clinical, financial and logistical perspective. Therefore, agreed interim funding may provide a path to full implementation of the NICE recommendation.
69. Given operational and other policy considerations, we envisage that the offer of 'interim funding' will only be made for medicines recommended by NICE that would be commissioned in the context of a prescribed specialised service. Please click [here](#) to find out more information about specialised services.
70. In the same way that the CDF operates, any company that wishes to take up the offer of Innovative Medicines Fund interim funding will need to agree to the Innovative Medicines Fund ECM described in the next section. If a company does not, such funding will not be made available.
71. 90 days after NICE issues final guidance (or within 30 days for medicines with EAMS designation) funding will switch permanently from the Innovative Medicines Fund to routine commissioning budgets, at which point companies will no longer be bound by the ECM.

(g) Financial control

72. To ensure the financial sustainability of the Innovative Medicines Fund, an Expenditure Control Mechanism (ECM) will be in place to enable the Innovative Medicines Fund to operate within a fixed budget. The ECM encourages companies to develop the most competitive CAA and incentivises relevant data generation and publication in as short a time as possible. The ECM aims to ensure that the NHS can secure maximum benefit for patients from its expenditure on these medicines, while more data is obtained on their effectiveness.
73. The ECM will ensure that, in the event the Innovative Medicines Fund budget is overcommitted at the end of a financial year, those companies that have had medicines funded through the Innovative Medicines Fund pay a

proportional rebate to NHS England. The proportions will be a pro-rata calculation of the spending on each company's medicines as claimed by NHS trusts.

74. The Innovative Medicines Fund is a managed access fund; NHS trusts are reimbursed for the cost of the medicine only. These reimbursements may vary from the amounts paid to companies for medicines purchased because of, for example, VAT, the weight of the patient and wastage charges, as appropriate.
75. Up to 2% of the Innovative Medicines Fund budget may be used to support the administration of the Innovative Medicines Fund (capped at a maximum of 2% of the fixed Innovative Medicines Fund budget).
76. Costs associated with MAAs in place outside of the Innovative Medicines Fund before the establishment of the Innovative Medicines Fund will continue to be funded separately and the medicines they relate to will not enter the Innovative Medicines Fund. Expenditure under these historic MAAs will not be subject to any ECM.

Appendix 1: Glossary

BIT: Budget Impact Test	HTA: Health Technology Assessment
CAA: Commercial Access Agreement	Interim funding: IMF funding for a NICE recommended medicine can start at the point NICE issues a draft positive final guidance.
CCG: Clinical Commissioning Group	MAA: Managed Access Agreement
CDF: Cancer Drugs Fund	Managed access period: The duration of a managed access agreement, including both the data collection period and the time required for the NICE guidance update.
DCA: Data Collection Agreement	MTA: Multiple Technology Appraisal
Data collection period: The time specified in the data collection agreement that covers the period of data collection and time for analytical outputs to be developed.	NICE: National Institute for Health and Care Excellence
EAMS: Early Access to Medicines Scheme	PAS: Patient Access Scheme
ECM: Expenditure Control Mechanism	QALY: Quality-Adjusted Life Year
HST: Highly Specialised Technologies	STA: Single Technology Appraisal

NHS England and NHS Improvement
 Skipton House
 80 London Road
 London
 SE1 6LH

This publication can be made available in a number of other formats on request.

© NHS England and NHS Improvement 2022

Publishing approval reference: PAR1686