Classification: Official

Publication approval reference: PR00301

MedTech Funding Mandate policy

Guidance for NHS commissioners and providers of NHS-funded care

Version 2, August 2023

Changes from previous version have been highlighted in yellow

Contents

Equality and health inequalities

1. Promoting equality and addressing health inequalities are at the heart of NHS England's values.

2. Through research and innovation, we can make an important contribution to reducing health inequalities by ensuring equitable and widespread access to proven innovations for all, and the adoption of innovations that proactively address and reduce inequalities in healthcare experience or outcomes.

3. The MedTech Funding Mandate (MTFM) policy works to address health inequalities in three ways:

    - striving for equitable access by ensuring all eligible patients can access the latest proven cost-saving NICE technologies; access to their use across England is mandated through the MTFM funding mechanism
    - ensuring our approach facilitates access by disproportionately affected groups as identified by the Core20PLUS5 approach
    - including technologies that treat conditions that disproportionately affect certain patient groups, such as patients with sickle cell disease.

4. Local commissioners and providers have a central role in using innovation to reduce inequity in patient access, experience and outcomes through the implementation of the MTFM policy.

5. The Innovation, Research and Life Sciences (IRLS) Patient and Public Involvement team empower patient groups and charities by communicating information on the new treatments supported by the MTFM policy. This helps patients understand what the best treatments are that should be available to them from their healthcare provider and supports them to have informed discussions with their clinicians.

Introduction

6. In the NHS Long Term Plan, NHS England outlined how research and innovation would drive better outcomes and experience for patients. An important element was the commitment to introduce a MedTech Funding Mandate (MTFM) policy to accelerate the uptake of selected National Institute for Health and Care Excellence

(NICE)-approved, cost-saving medical devices, diagnostics and digital products in the NHS, meaning patients will get access to these technologies across England by removing funding barriers. The MTFM policy was launched in April 2021 with this document providing a policy update, effective from 1 April 2023.

7. The Life Sciences Vision, published in July 2021, set out the government's ambitions to build on scientific successes and tackle future challenges. It recognised the opportunity to accelerate the development of MedTech tools and get them to patients more quickly, and refers to the MTFM policy as playing a critical role in addressing the most pressing needs of the NHS in England.

8. The MTFM policy builds on prior NHS Accelerated Access Collaborative (AAC) innovation programmes, such as the Innovation and Technology Tariff/Payment programme (ITT/ITP), introduced to address financial and procurement barriers to the adoption of devices, diagnostics and digital products.

9. The aim of the MTFM policy is to accelerate equitable patient access to medical technologies that are clinically effective, cost saving in 3 years (as determined by NICE) and affordable to the NHS (costs not exceeding £20 million), by supporting their implementation and then scaling them (adoption and spread).

10. To achieve the aim, the objectives of the MTFM policy are to:

    i. mandate commissioners to fund the MTFM technologies when clinically appropriate

    ii. ensure equity in healthcare provision is achieved by monitoring patient access to the supported technologies across the NHS in England

    iii. direct the NHS on which MedTech innovations are effective and likely to give savings on investment

    iv. support the NHS to develop a sustainable approach to overcoming the financial barriers to adopting medical devices, diagnostics and digital products.

11. In preparation for 2023/24, the MTFM Policy team have worked with NICE and other key partners to assess all available medical technology guidance and diagnostic guidance. They have also considered current NHS operational pressures and the transition to new commissioning structures with the advent of integrated care systems (ICSs) on 1 July 2022.

12. No additional technologies will be added to the MedTech funding mandate for 2023/24. Systems should prioritise the appropriate adoption of current supported technologies, which offer cost savings and improved patient outcomes and experiences.

13. This decision will ensure that the MTFM does not add to the sector's burden as it continues to embed ICSs and the new commissioning relationships that underpin system working. The IRLS group, along with NICE, NHS Supply Chain and the academic health sciences networks (AHSNs; to be renamed health innovation networks from 1 October 2023), will continue to support national adoption of the supported technologies.

14. The MTFM policy is for NHS providers and their commissioners in England, and explains:

    i. the scope of the MTFM policy
    ii. which technologies are included
    iii. the implementation support available via NICE tools and resources, the AHSNs and NHS England
    iv. the roles and responsibilities of NHS providers, NHS commissioners and suppliers of technologies, and how they will be supported by the MTFM policy and the AHSNs
    v. plans for performance and evaluation, and compliance monitoring.

Scope

15. The MTFM policy was launched on 1 April 2021. This updated guidance replaces previous versions and is effective from 1 April 2023.

16. NHS England's IRLS team and NICE assessed relevant guidance to understand which technologies met the criteria for inclusion in the 2022/23 MTFM policy. NHS England will continue to consider technologies proven to be clinically effective and cost-saving for inclusion in updates of this policy, with support from NHS providers, NHS clinical commissioners, NHS Supply Chain, the Department of Health and Social Care, Patient and Public Voices, industry representatives and representative bodies.

17. Policy guidance will be reviewed in year to assess the impact of any legislative change arising from the Health and Care Bill.

18. In the NHS Standard Contract, General Service Conditions, section 2.2 states that "The Parties must comply, where applicable, with their respective obligations under, and with recommendations contained in, MTFM guidance".

Criteria for inclusion in the MedTech Funding Mandate

19. In 2023/24, we will review published NICE guidance to identify devices, diagnostics or digital products that:

    i. **are effective:** demonstrated through a positive NICE guidance[1, 2]

    ii. **are cost-saving within 3 years:** NICE modelling demonstrates a net saving in the first 3 years of implementing the technology[3]

    iii. **are affordable to the NHS:** the cost should not exceed £20 million in any of the first 3 years.[4]

Notes:

[1] Please refer to information on NICE guidance.

[2] We reserve the right not to include a technology in the MTFM policy and/or to undertake further negotiations with technology suppliers if additional data collection is required to demonstrate sustained effectiveness.

[3] Demonstrated by a NICE published resource impact assessment (RIA).

[4] We reserve the right not to include a technology in the MTFM policy and/or to undertake further commercial negotiations with manufacturers if we believe the £20 million cost limit will be exceeded in any of the first 3 years.

20. NHS England works closely with NICE to ensure that the MTFM criteria align with future changes to the medical technology evaluation process and subsequent guidance publication process.

21. Any changes to the MTFM criteria will be signalled on the MTFM webpage and published in the subsequent version of the MTFM policy guidance.

2023/24 MedTech Funding Mandate technologies

22. The MTFM continues to support the technologies selected for support in 2021/22 and 2022/23. The technologies from 2021/22 are:

- **placental growth factor-based testing (PLGF) (DG49)**[1] – a diagnostic test to help rule out pre-eclampsia (Triage PlGF test and the Elecsys immunoassay sFlt-1/PlGF ratio)
- **SecurAcath (MTG34)** – for securing percutaneous catheters
- **HeartFlow FFRCT (MTG32)** – for estimating fractional flow reserve from coronary CT angiography
- **gammaCore (MTG46)**[2] – a handheld device which alleviates the symptoms of severe cluster headaches by stimulating the vagus nerve.

Notes:

[1] DG49 replaced DG23, which has been supported by the MTFM policy since 2021. DG49 was published on 27 July 2022. Currently the MTFM policy only supports two of the three technologies recommended in DG49.

[2] NICE will review MTG46 in 2023. Find out how to register as a stakeholder here.

23. NHS England is reviewing the level of support required for these four technologies going forward. The outcome of this review will be signalled on the policy webpage.

24. Since 2022/23, the policy has supported seven technologies. Four of these are an alternative treatment to transurethral resection of the prostate (TURP) for benign prostatic hyperplasia:

- **GreenLight (MTG29)** – uses a laser to reduce the size of an enlarged prostate
- **Rezum (MTG49)** – uses water vapour to destroy excess prostate tissue
- **Plasma System (MTG53)** – uses electrodes to cut out prostate tissue
- **UroLift (MTG58)** – lifts and holds the enlarged prostate tissue away from the urethra, relieving the compression of this organ.

25. The remaining three technologies supported from 2022/23 are an alternative to more invasive procedures:

- **Spectra Optia (MTG28)** – apheresis and cell collection platform for people with sickle cell disease who require automated red cell exchange
- **XprESS Multi Sinus Dilation System (MTG30)** – a sterile, single-use device for treating chronic sinusitis with a dilating balloon
- **Thopaz+ (MTG37)** – a portable digital chest drain system that accurately monitors and records air leak and fluid drainage.

26. Further detail on these technologies can be found in Annex 1.

27. Newly published NICE guidance is assessed to understand if the technology meets the criteria in paragraph 19. The MTFM team also carry out assessments to ensure the technology:

- aligns to NHS England's priorities
- is supported by NHS clinical leads
- aligns to Get It Right First Time programmes
- is suitable for use in the acute sector.

28. Once a technology is understood to be suitable for support under the policy, it will be signalled on the policy webpage to enable the sector to prepare for its inclusion in activity planning.

29. With NICE, we will continue to monitor the spread, adoption and real-world evidence from the implementation of these technologies, and compare this with published NICE guidance and tools.

30. Should a technology no longer meet the criteria for policy support, this finding will be communicated on the policy webpage.

31. For all technologies supported under the MTFM policy, please refer to the NICE guidance to understand implementation eligibility.

32. Technologies are funded by local commissioners from existing allocations, except for Spectra Optia.

33. Spectra Optia is for the treatment of sickle cell disease, which is part of the Blood and Infection National Programme of Care (NPoC) that provides leadership and oversight of haemoglobinopathies. NHS England commissions these services. Therefore, Spectra Optia costs will be funded from existing NHS England allocations.

34. A Spectra Optia working group has been created to ensure that patients with sickle cell disease have access to automated red cell exchange procedures, particularly out of hours. The group are working with the 10 haemoglobinopathy co-ordination centres and the National Blood Transfusion Service to understand where additional capacity and out-of-hours access to the equipment are needed,

and how this can be supported by NHS England Specialised Services commissioning.

35. Providers that want to know more about this should contact the MTFM inbox england.medtechfundingmandate@nhs.net in the first instance.

Communication of future changes to MTFM policy criteria and products

36. The technologies already covered by the MTFM policy will be subject to review to determine if any should be removed, including those for which NICE guidance has been significantly updated; alternative treatment or diagnostic options exist; or significant safety concerns have been raised. If any technologies are to be withdrawn, this will be signalled ahead of further policy publication, via the policy webpage.

37. Removal of technologies will be signalled in year via the policy webpage, giving commissioners and providers that may be impacted by the change time to prepare.

38. Changes will also be referenced in the annual NHS operational planning and contracting guidance.

39. The technologies covered by the MTFM policy will be updated annually in related NHS England publications, including the NHS Payment Scheme and NHS Standard Contract. These are typically published on the NHS England website between December and March and are subject to their own consultation processes.

40. The MTFM policy will be updated in line with any relevant and significant legislative changes.

41. We invite stakeholders to join our FutureNHS page to get the latest updates on the MTFM policy, including information on engagement events, the technologies supported and planned publications, including the signalling of the next year's technologies. Please log onto FutureNHS and search for the MTFM workspace to request membership.

NHS Payment Scheme

Financial impact

42. The MTFM policy does not provide additional funding for the technologies it supports. Instead, it mandates commissioners to fund the MTFM technologies when clinically appropriate. The MTFM policy criteria ensure that technologies are cost saving within 3 years, as estimated by the NICE Resource Impact Assessment (RIA) team.

43. The NICE RIAs for the seven technologies that met the criteria for 2022/23 and continue to do so in 2023/24 estimate that:

    - without implementation or continuation of use of these technologies, the cost of care would be around £498 million over 5 years
    - by implementing them, the cost of care reduces to £454 million over 5 years. Implementation would therefore achieve a net saving to the taxpayer of around £44 million over 5 years.

44. The savings analysis from NICE can be found in Annex 2.

45. NICE also produces tools to help providers and commissioners understand the impact on their patient population; see Annex 1.

NHS National Payment Scheme 2023/25

46. Changes to the payment mechanisms will be included in the NHS Payment Scheme consultation. There were no changes to the funding mechanism for the MTFM policy in the consultation for 2023/25.

47. In the NHS Payment Scheme provider payments document, section 2.4 Excluded items explains the treatment of the costs of MTFM technologies.

48. This is further explained in Appendix 3 of the NHS provider payment mechanisms.

49. A guide to applying the NHS Payment Scheme to possible MTFM policy scenarios can be found in Annex 3.

Funding the cost of the technologies

50. The MTFM policy has a ‘pass through’ payment approach, where the commissioner is required to pay for the cost of MTFM technologies from existing

allocations on a ‘cost and volume’ basis. The MTFM technologies are from the national prices and a list of supported technologies are published in Annex A 2023/24 prices workbook, on tab 12c ‘MedTech FM products’ .

51. Items on the MedTech FM products list are subject to payment scheme local pricing rule 3, which stipulates that the price the commissioner pays must reflect actual costs, the prices set under any applicable procurement framework or a reference price set by NHS England, whichever is the lowest.

52. For 2023/24 NHS England will not set any reference prices for the technologies supported; therefore, actual cost should be reimbursed by commissioners to providers.

Funding the capital purchase

53. Technologies supported by the policy that are capital purchases, eg Spectra Optia apheresis machine, should be added by providers to their priority capital spend list. On the completion and approval of a business case, the depreciation should be reimbursed by the commissioner.

Funding the cost of implementation

54. Pass through payment of the technologies does not include implementation or running costs: this was highlighted as a barrier to adoption. Therefore, as part of the NHS provider payment mechanisms, the payment policy states that the API fixed payment between commissioners and providers should include all known upfront implementation costs in 2023/25.

55. AHSNs have been commissioned to support local systems with implementation plans and can help providers understand the implementation costs of the different technologies.

Tools to support commissioner agreements

56. The NHS England innovation payment project developed guidance to help commissioners and providers navigate through the NHSPS for 2023/25. Providers and commissioners need to understand the cost of both implementation and any potential running costs of introducing a new technology to a specialty, to include these costs in the fixed element of their agreements.

57. Annex 3 explains how the payment mechanisms can be applied to different MTFM implementation scenarios.

58. NICE provides tools and resources as part of the published guidance to help with this. NHS England, the AHSNs and technology suppliers will build business cases and case studies to help understand the technologies and their benefits; these will be available on the FutureNHS page.

National Cost Collection 2023

59. The 2023 National Cost Collection will include cost and activity data for the technologies supported in the policy.

60. The four technologies supported in 2021/22 were all centrally funded by the ITP programme, where payments were made directly to the supplier at zero cost to providers. From April 2021, it was the providers responsibility to pay for the technologies themselves, meaning the cost of the technologies have become visible and can be included in local service-line reporting (SLR) information and in the National Cost Collection data in 2023. (Note: SLR is not mandated and frequency of reporting is locally determined. Please contact your provider's costing team for more information.)

61. As part of an update to the costing standards, NHS England has added functionality to the integrated technical document to enable providers to identify the technologies supported by the MTFM policy in their cost data.

62. A new collection resource code was added to the National Cost Collection from 2022, and NHS provider costing practitioners should use this to identify on submission the cost of the technologies supported by the MTFM policy. The collection resource code will enable NHS England to analyse the use of the technologies nationally and facilitate benchmarking and opportunity analysis within The Model Health System, a data-driven improvement tool enabling quality and productivity benchmarking.

63. National cost data will also enable local and national analysis to demonstrate the cash-releasing and resource-saving benefits from adopting the technologies in the policy.

Procurement of MTFM technologies

64. Technologies included in the MTFM policy should be procured through the relevant NHS Supply Chain framework, giving providers a procurement route that means they do not have to negotiate individually with suppliers.

65. NHS England is working with NHS Supply Chain to understand the feasibility of moving to a more robust reporting mechanism. Updated guidance will be issued and any developments will be communicated on the policy webpage and the FutureNHS page.

66. Providers of NHS-funded services can set up an NHS Supply Chain account via the online catalogue and ordering accounts webpage.

67. Non-NHS providers of NHS-funded services can apply for an NHS Supply Chain account via the create an account webpage.

68. NHS Supply Chain's guidance notes to its online catalogue and ordering provides step-by-step guidance for ordering via the NHS Supply Chain online catalogue.

Performance and evaluation

Spread and adoption of MTFM technologies

69. NHS England will review the stage of adoption of MTFM technologies, by provider site, using the AHSN Quarterly Assurance Reporting Tool (QART). This informs the reporting for the MTFM Dashboard, which is published on FutureNHS page (access will need to be requested) and used to demonstrate the stage of adoption each provider is at for each MTFM technology.

70. The reporting identifies which providers and commissioners have yet to adopt, supporting discussion on their current barriers and helping them learn from other providers and commissioners that have successfully adopted.

71. NHS England is working to strengthen the data reporting using sales data reported by the supported technology suppliers. Work to develop intelligence on the impact of the MTFM technologies is ongoing. Updates on this work will be published on the policy webpage and FutureNHS page.

Monitoring compliance

72. The 2023/24 NHS Standard Contract will "require both commissioners and providers of NHS-funded services to comply, as relevant, with their obligations under, and any recommendations contained in, the MedTech Funding Mandate". This builds on the existing contractual requirement to have regard for guidance published by NICE. To be compliant, we would expect eligible patients to be able to access the technologies supported by the policy.

73. Patients have the right to access drugs and treatments that have been recommended by NICE for use in the NHS, if their doctor says they are clinically appropriate for them in accordance with the NHS Constitution for England.

74. Compliance is not relevant where the NICE recommendations are not relevant to the organisation (eg the provider does not provide services for the specific patient cohort the technology supports, or an alternative treatment is more appropriate for that patient).

75. Technologies included in the MTFM policy have been proven to support safe and effective care and their use by a service can be used as evidence by the Care Quality Commission (CQC) that a provider is meeting its regulatory requirements.

76. Together with the strengthened NHS Standard Contract requirement to comply with the MTFM, and patient awareness that these technologies must be a treatment option in line with NICE recommendations, providers may wish to review how they demonstrate their compliance with the MTFM.

77. Examples of how NHS commissioners and providers of NHS-funded services can evidence compliance with MTFM policy guidance include:

    i. ICS publishing policy statements, service-level agreements and/or contracts to demonstrate funding is in place and that they require innovations covered by the MTFM policy to be available for use, in consultation with the patient and when recommended by NICE as part of their treatment pathway.

    ii. Providers of NHS-funded services publishing their policies and clinical care pathways to demonstrate that innovations covered by the MTFM policy are available and evidenced as part of the safe, effective and/or well led sections of the CQC assessment framework.

iii. Organisations publishing audit data and patient surveys to demonstrate the use of technologies covered by the MTFM policy.

78. We will continue to work with the AHSNs and NHS Supply Chain to track the uptake of the technologies covered by the MTFM policy. Uptake data will be included in the MTFM Dashboard and monitored through the AAC Board. When NHS England is made aware of non-compliance, we will seek to engage with the relevant providers and commissioners to provide support, and understand barriers and how to overcome these. This is to ensure the MTFM policy aim of equitable health access across England is achieved.

Implementation support

Academic health science networks

79. Providers of NHS-funded services and NHS commissioners have access to implementation support from the 15 AHSNs across England (to be renamed health innovation networks from 1 October 2023).

80. NHS England established the AHSNs in 2013 to spread innovation, improve health and generate economic growth. Each AHSN works across a distinct geography and is connected to the regional and local NHS structures.

81. AHSNs connect NHS and academic organisations, local authorities, charities and industry, and provide a range of practical support to facilitate change across health and social care economies.

82. The AHSNs have extensive experience of implementing these technologies in the NHS, having supported the national adoption and spread component of the ITT/ITP programmes.

83. The AHSNs can link provider clinical teams to the corporate teams and commissioners, assist planning discussions and support business case development for initial and/or sustained adoption.

84. To contact your local AHSN for support, please visit its website.

NICE tools and resources

85. NICE develops tools to help providers of NHS-funded services implement NICE guidance. These include:

    i. costing statements/resource impact reports explaining the resource impact guidance

    ii. resource impact templates to help local areas assess the financial impact of the guidance

    iii. general implementation materials outlining how to put guidelines into practice

    iv. specific examples, developed with providers that have implemented the technologies, which include:

        - plain language 'information for the public' summaries of the technologies
        - shared learning case studies from NHS organisations that have implemented the technologies
        - checklists
        - data protection agreements.

86. Links to the NICE implementation support materials for these technologies are provided in Annex 1.

Roles and responsibilities

87. This section describes the roles and key responsibilities for MTFM policy stakeholders including:

    - suppliers of technologies included in the policy
    - NHS England
    - AHSN technology leads
    - individual AHSNs
    - NHS providers – corporate teams
    - NHS providers – clinical teams
    - NHS commissioners.

Suppliers of technologies supported by the MedTech Funding Mandate

88. Technology suppliers are expected to:

- consider additional resource and capacity for the scaling up of their business to meet increased demand if this is relevant
- produce high quality business cases for commissioner funding if providers require funding to purchase the technology
- work with NHS Supply Chain in readiness for the effective date and onboard their respective providers
- support AHSNs with relevant communications and engagement including action learning sets; and support clinicians in relevant discussions involving the technology
- adhere to the code of conduct as set out by the Association of British HealthTech Industries (ABHI) or MedTech Europe, and respect that being included in the MTFM policy is not a sales opportunity, and the focus is on equitable patient access
- work with the MTFM Policy team and IRLS Performance and Evaluation team to monitor patient access by sharing sales data.

NHS England

89. NHS England is expected to:

- engage with NICE, AHSNs, Supply Chain Coordination Ltd (SCCL; the management function for the NHS Supply Chain operating model) and NHS Supply Chain to develop and improve MTFM policy documents and operational processes
- produce MTFM policy documents, tools and engagement pieces, including patient and public involvement
- prepare AHSN leads and suppliers for the policy effective date by sharing knowledge on NHS processes including, but not limited to, procurement and funding mechanisms
- support non-compliance resolution to ensure the aims of the MTFM policy are being met
- support resolution of issues should any concerns be raised in relation to the technology suppliers' business conduct.

AHSN technology leads

90. AHSN technology leads are expected to:

- lead AHSN baselining activity for technologies to understand current uptake across England and work with NICE on findings
- develop a suite of implementation support tools for all AHSNs and system stakeholders to use in product adoption and spread, including an implementation toolkit and business case template, by working with NICE and the product supplier
- be the focal point for gathering learning from across the AHSNs on barriers and success stories
- help overcome clinical barriers to adoption by offering advice and guidance to all AHSNs, working with clinical champions where appropriate
- work with NHS England to develop case studies and deliver engagement pieces, including webinars, to support implementation and spread
- report national progress to the AHSN National Programme Director to support governance processes.

Individual AHSNs

91. Individual AHSNs are expected to:

- support business case production by sharing templates and examples, and with quality assurance
- understand adoption status across all eligible provider sites
- raise awareness of MTFM policy and products across the local system
- be honest brokers between product suppliers and NHS teams
- share best practice in implementation from other NHS systems
- support collection of evidence to demonstrate impact of the product
- when alternative technologies to those supported by the MTFM policy are in place, support the collation of evidence to demonstrate equivalent outcomes for discussion with the IRLS team and NICE
- capture and report barriers and issues across the AHSNs (the 15 individual AHSNs) to share with the IRLS team and NICE
- escalate non-compliance to the IRLS team by sharing all available knowledge and understanding.

NHS providers – corporate teams

92. Provider corporate teams are expected to:

- familiarise themselves with the MTFM policy guidance
- work with AHSN and local teams to understand which technologies their health system is eligible to provide (NICE guidance, tools and resources will assist this)
- engage with NHS England National Payment Scheme guidance, tools and communications that support the MTFM policy
- work with commissioners to understand the initial funding requirements to implement technologies, future financial benefits and the value of future capacity benefits
- collaborate with AHSN and clinical teams to understand the technologies and their respective benefits to services
- engage commissioning and costing teams to plan current and future contracting arrangements that include the MTFM technologies
- join the MTFM FutureNHS workspace to be aware of any planned engagement events and policy developments.

NHS providers – clinical teams

93. Provider clinical teams are expected to:

- collaborate with AHSNs and suppliers to understand the technologies and their respective benefits to services
- engage with their corporate teams to help them understand which technologies the provider is eligible to provide in line with NICE guidance (see Annex 1)
- raise patient awareness of new available treatments and their benefits to patients
- work with specialty clinicians to prepare for changes to care pathways
- agree the expected level of activity for each technology
- promote service improvements with primary care services
- record outcomes and benefits data achieved through technologies and share this appropriately

- join the MTFM FutureNHS workspace, which provides updates on planned engagement events and policy developments.

NHS commissioners (ICSs)

94. NHS commissioners (ICSs) are expected to:

- familiarise themselves with the MTFM policy guidance
- engage with NHS England National Payment Scheme guidance, tools and communications that support the MTFM policy
- identify local patient populations that technologies will benefit (using NICE resource impact templates)
- engage with providers to agree projected activity and how this fits in with contractual arrangements
- work with providers and ensure funding is made available
- monitor evidence of spread and adoption, and benefits to patients
- join the MTFM FutureNHS page, which provides updates on planned engagement events and policy developments.

Annex 1: Innovations supported by the MedTech Funding Mandate

HeartFlow (MTG32)

HeartFlow FFRCT estimates fractional flow reserve from coronary CT angiography (CCTA) for patients with stable, recent-onset chest pain.

NICE medical technologies guidance (MGT32): HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography

HeartFlow® product website

Clinical benefit (as stated by NICE)

HeartFlow FFRCT is as accurate as CCTA in excluding coronary artery disease and characterises the coronary arteries from both functional and anatomical perspectives, differentiating between ischaemic and non-ischaemic vessels in a way that CCTA cannot. The coronary lesions responsible for coronary artery disease can be identified without the need for invasive procedures and further non-invasive tests.

Patient benefit (as stated by NICE)

- Replaces the need for an invasive procedure in a specialist cardiology procedure suite.
- Reduced length of stay.
- Reduced hospital visits as multiple diagnostic tests such as exercise tests and stress tests are not required.
- Faster diagnosis.
- Reduced waiting times for patients waiting for a procedure in the specialist cardiology procedure suite.

SecurAcath (MTG34)

SecurAcath is a device to secure peripherally inserted central catheters (PICCs) and should be considered for any PICC with an anticipated medium to long-term dwell time (15 days or more).

NICE medical technologies guidance (MTG34): SecurAcath for securing percutaneous catheters

SecurAcath product website

Clinical benefit (as stated by NICE)

SecurAcath is easy to insert, well tolerated, associated with a low incidence of catheter-related complications and does not usually need to be removed while the catheter is in place. Clinical benefits include no interruptions or delays from the catheter becoming dislodged. SecurAcath improves vessel preservation and reduces need for re-insertions. There are also fewer complications such as migration, thrombosis and infection.

Patient benefit (as stated by NICE)

- No risk of medical adhesive-related skin injury.
- No requirement for frequent adhesive fixing changes.
- Reduced risk of interruption to treatment.
- Reduced risk of catheter-related infection.
- Reduced pain on insertion and while in situ.

gammaCore (MTG46)

gammaCore (electroCore) is a non-invasive vagus nerve stimulator used to treat and prevent cluster headaches. It is self-administered by the person or their carer.

NICE medical technologies guidance MTG46: gammaCore for cluster headache

gammaCore product website

Clinical benefit (as stated by NICE)

Clinical evidence shows that, for some people, using gammaCore as well as standard care reduces the frequency and intensity of cluster headache attacks and the need for medication. This is likely to significantly improve quality of life for people living with this condition.

Patient benefit (as stated by NICE)

- Significant quality of life improvement from reduced pain during an attack.
- Reduced need for expensive medication.
- Reduced hospital visits.

PLGF (DG49)

Placental growth factor (PLGF)-based tests are intended to be used with clinical judgement and other diagnostic tests, to help rule out suspected pre-eclampsia. This assessment focuses on ruling out pre-eclampsia in the second and third trimesters of pregnancy.

NICE diagnostic guidance DG49: PLGF-based testing to help diagnose suspected pre-eclampsia

Roche Elecsys sFlt-1 PLGF product website

Quidel Triage PLGF product website

Clinical benefit (as stated by NICE)

Using PLGF-based tests in addition to standard clinical assessment promotes better risk assessment for adverse outcomes in women with suspected pre-eclampsia. It allows people in whom pre-eclampsia has been ruled out with a PLGF-based test to return to community care instead of being admitted to hospital for observation.

Patient benefit (as stated by NICE)

- Reduced length of stay if patient already admitted.
- Admission avoidance if test carried out without admission to hospital.
- Reduced need for further third trimester scans.
- Increased assurance reduces stress for patients.

UroLift (MTG58)

The UroLift system is an implanted device which lifts and holds enlarged prostate tissue away from the urethra, relieving the compression of this organ. It can be implanted under local anaesthesia in an outpatient setting or ambulatory care centre, and the patient can return home the same day without a catheter.

NICE Medical technologies guidance (MTG58): UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia

UroLift® product website

Clinical benefit (as stated by NICE)

UroLift relieves lower urinary tract symptoms for up to 5 years. It also improves quality of life and avoids risk to sexual function.

Patient benefit (as stated by NICE)

- It is for people aged 50 and older with a prostate of 30 to 80 mL.
- The procedure is minimally invasive, so open surgery is not needed, and it does not affect sexual function.
- It can usually be implanted without an overnight stay in hospital, allowing the patient to return home without a urinary catheter.

GreenLight XPS (MTG29)

GreenLight XPS vaporises prostatic tissue with a laser. The laser fibre is passed through a cystoscope to photoselectively vaporise the enlarged prostate tissue, leaving a clear urethral channel. GreenLight XPS can be done as a day-case procedure, reduces the risk of complications and allows a quicker return to normal activity.

NICE Medical technologies guidance (MTG29) GreenLight XPS for treating benign prostatic hyperplasia

Boston Scientific GreenLight™ product website

Clinical benefit (as stated by NICE)

GreenLight XPS uses a laser to reduce the size of an enlarged prostate, easing the symptoms of benign prostatic hyperplasia (BPH).

Patient benefit (as stated by NICE)

- Can more often be done as a day-case procedure (patients can go home on the same day as the procedure is done).
- It allows patients to get back to normal day-to-day activities quicker after the procedure.

Rezum (MTG49)

Rezum is a minimally invasive procedure that uses water vapour (steam) to treat BPH. The technology delivers targeted, controlled doses of stored thermal energy in water vapour directly to the region of the prostate gland with the obstructive tissue causing lower urinary tract symptoms (LUTS).

Rezum effectively alleviates BPH and patients can be treated as outpatients.

NICE Medical technologies guidance (MTG49): Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia

Boston Scientific Rezum™ product website

Clinical benefit (as stated by NICE)

Rezum uses water vapour to destroy excess prostate tissue with the aim of relieving symptoms. The process is intended to disrupt cell membranes, leading to cell death and shrinking the prostate. The intention is to relieve obstructive symptoms without interfering with surrounding tissues that might impair sexual function.

Patient benefit (as stated by NICE)

- Relieves symptoms.
- Improves quality of life.
- Minimally invasive, which means open surgery is not needed.
- Unlikely to need a stay overnight in hospital.

PLASMA System (MTG53)

PLASMA is a bipolar electrosurgery system for TURP. The system uses electrodes to cut out (resect) prostate tissue and stop any local bleeding afterwards (haemostasis), which avoids the risk of transurethral resection syndrome and reduces.

NICE Medical technologies guidance (MTG53): The PLASMA system for transurethral resection and haemostasis of the prostate

Olympus PLASMA+ System product website

Clinical benefit (as stated by NICE)

PLASMA avoids the risk of transurethral resection syndrome and reduces the need for blood transfusion. Clinical outcomes are as good as for conventional monopolar TURP but there is a lesser chance of serious complications.

Patient benefit (as stated by NICE)

- Less chance of serious complications.
- Reduces the length of hospital stay.
- This procedure can be done as a day case.

XprESS multi-sinus dilation system (MTG30)

The XprESS multi-sinus dilation system is a sterile, single-use device for treating chronic sinusitis. Dilation of the XprESS balloon remodels the bony sinus outflow tract by displacing adjacent bone and paranasal sinus structures. This has the potential to reduce the tissue lost compared to traditional functional endoscopic sinus surgery (FESS) procedures.

NICE Medical technologies guidance (MTG30): XprESS multi sinus dilatation system for treating chronic sinusitis

Stryker XprESS product website

Clinical benefit (as stated by NICE)

XprESS is a clinically non-inferior, but less invasive, alternative to FESS in patients with uncomplicated chronic sinusitis. Compared with FESS, it may lead to faster recovery times and carries a lower risk of some complications. It has the potential to treat uncomplicated chronic sinusitis earlier in disease progression than is currently available in the NHS. As such, it may improve quality of life and clinical outcomes, as well as reduce surgical waiting lists.

Patient benefit (as stated by NICE)

- An option for chronic sinusitis that has worsened despite drug treatment.
- May be beneficial for uncomplicated chronic sinusitis, because it can be done more often under local anaesthesia.
- May allow the patient to recover faster than after surgery.

Thopaz+ portable digital system (MTG37)

Thopaz+ is a portable digital chest drain system that provides regulated negative pressure close to the patient's chest and continuously monitors and records air leak and fluid drainage. The system comprises an inbuilt, regulated suction pump with a digital display, rechargeable battery, tubing that connects to any standard chest drain catheter and a Thopaz+ disposable fluid collection canister.

NICE Medical technologies guidance (MTG37): Thopaz+ portable digital system for managing chest drains

Medela Thopaz+ product website

Clinical benefit (as stated by NICE)

Sensors in the system turn the pump on and off to ensure the pressure level set by the healthcare professional is precisely maintained. Provides objective measurements of air leakage and fluid loss. This data makes it easier to assess and record patients' progress. This in turn may help clinicians determine when it is best to remove the chest drain.

Patient benefit (as stated by NICE)

- Reduces drainage time.
- Reduces length of stay in hospital.
- Allows people to stay mobile during their treatment.
- Improves safety.

- Patients may also need fewer chest X-rays with the use of Thopaz+.

Spectra Optia (MTG28)

The Spectra Optia Apheresis System is an apheresis and cell collection platform for the treatment of sickle cell disease. In a typical exchange procedure, Spectra Optia separates and removes sickle red blood cells from the patient's blood using continuous flow and centrifugation. These are replaced with healthy red blood cells according to the user-defined software protocol.

NICE Medical technologies guidance (MTG28): Spectra Optia for automatic red blood cell exchange in people with sickle cell disease

https://www.terumobct.com/spectra-optia

Clinical benefit (as stated by NICE)

Faster and needs to be done less often than manual red blood cell exchange.

Patient benefit (as stated by NICE)

- Faster and needs to be done less often than manual red blood cell exchange.

Annex 2: Estimated resource impact over 5 years according to NICE resource impact assessments

Product	Estimated cost of current practice	Estimated cost of future practice (Y5)	Resource impact (Y5)
	£	£	£
HeartFlow	67,155,804	64,677,299	2,478,504
SecurAcath	5,345,157	2,799,535	2,545,622
PLGF	22,193,000	17,926,527	4,266,473
gammaCore	216,891,554	214,089,845	2,801,709
GreenLight Rezum PLASMA System UroLift	80,184,845	68,095,210	12,089,636
XprESS	21,752,425	16,221,856	5,530,569
Thopaz	57,798,050	48,183,361	9,614,689
Spectra Optia	27,156,262	22,036,283	5,119,980
Total	**498,477,099**	**454,029,916**	**44,447,183**

Annex 3: A practical guide to MTFM payment mechanisms

Background

1. Over the past 2 years, the MTFM Policy team have sought feedback from AHSNs, providers and commissioners on the practicalities of implementing the policy. This has generated substantial learning on the challenges systems face in establishing how supported technologies can be funded (and their benefits realised).

2. In response to this feedback, this annex provides a practical guide to support providers, commissioners and other key policy stakeholders in seeking solutions when discussing how to fund MTFM supported technologies in different funding scenarios.

3. The NHS Payment Scheme recommends use of blended payments, which is a NHS Long Term Plan commitment (see page 101). On this basis, the MTFM requests providers and commissioners together explore how supported technologies can be funded and savings can be realised.

4. In some cases, particularly where ICS/ICB relationships are still being established, alternative funding arrangements have been agreed. This notably includes use of block contracting between providers and commissioners, whereby providers are assigned rigid fixed payments, which do not have the flexibility of the prospective fixed payments advocated in NHS provider payment mechanisms.

5. Two reasons behind this continued use of rigid fixed payments may be:

   a. to manage budgets more tightly where systems are in deficit

   b. to ease the transition to ICSs/ICBs by sustaining previous funding practices.

6. Use of fixed payments with no variable or additional elements has posed a barrier to MTFM supported technology adoption, particularly where systems are in deficit. There is a lack of clarity about how the impact of historical funding arrangements to support MTFM technology adoption should influence the funding of current or future technologies. NHS England has received feedback that some systems are agreeing fixed payments with no scope for pass through payments to cover technology costs, and no inclusion of MTFM technology-related implementation costs. Providers are therefore being told that if they want to adopt MTFM supported technologies, they must do so using pre-existing funds from the fixed payment.

ICS duty to adopt innovation

7. Where the MTFM financial mechanisms, which are designed to incentivise innovation, are not being used, the more rigid funding arrangements outlined above have been found to hinder adoption of supported technologies.

   Failing to adopt supported technologies where clinically appropriate contravenes the NHS Standard Contract (section 2.2) and NHS Payment Scheme guidance. ICBs have a duty, in exercising their functions, to promote innovation in the provision of health services, as described in section 13Z39 of the NHS Act 2006 (as superseded by section 25 of the Health and Care Act 2022). Agreeing payment with providers is part of their functions, so the legal duty to promote innovation applies, and innovation must be accounted for in payment arrangements (that is, agreeing fixed payments and pass through payments). Pages 13, 15 and 18 of NHS England's integrated care systems design framework provide more detail on this duty.

Funding provision

8. The recommended blended payment model between commissioners and providers is made up of a fixed payment, a variable activity-based payment (eg for elective care) and a low volume activity block payment for activity with an annual value of <£0.5 million. The cost of MTFM supported technologies is excluded from all these payments. Commissioners should instead reimburse providers for MTFM technology costs via pass through payments based on the cost and volume of technology use. The level of reimbursement for MTFM supported technologies is outlined in aligned payment and incentive rule 3, which is set out in section 4 of the NHS Payment Scheme guidance.

9. The fixed payment between commissioners and providers should also include an amount for any implementation costs not covered by pass through payments. Providers and commissioners should submit a variation to NHS England, using the required template, if they are not following this guidance.

10. Ideally, these arrangements should be agreed ahead of the start of each financial year so that fixed payments are set appropriately, and the commissioner can identify the funding required in year for pass through payments. If a provider has signed up to a fixed payment without these considerations, then it needs to identify how it will meet any funding requirements. No new technologies have been selected for MTFM support in 2023/24, to allow providers and commissioners to focus on adopting technologies selected for support in 2022/23. If the commissioner is not reimbursing the innovative products in accordance with the NHS Payment Scheme,

then it should submit a variation to NHS England, along with justification, using the required template.

11. Providers and commissioners should identify where necessary funding that could be made available; through using funding kept in reserve, or exploring whether any capacity benefit released from adopting MTFM supported technologies could be used to support use of the Elective Recovery Fund. If these two options are not possible, providers and commissioners should establish arrangements to ensure payment guidance is followed next year (2024/25) and revise service delivery plans to account for the effects of using the MTFM technologies. Providers and commissioners should work together to ensure financial risk is shared, especially when costs and benefits may sit in different parts of the system.

Next steps for AHSNs

12. This annex explains the expectation under the National Payment Scheme and MTFM policy that ICSs identify additional monies to fund MTFM technologies regardless of block contracting or historical MTFM-related funding arrangements.

13. AHSNs encountering this issue should share the narrative with their ICS stakeholders, together with this annex, to aid funding and commissioning conversations.

Transition from innovation technology payment

14. Payments to providers in the 2019/20 financial year were used as the basis for the special payment arrangements adopted in response to the COVID-19 pandemic, whereby most providers were moved onto block contract payments ‘on account’. The fixed payments allocated in 2023/25 use 2019/20 payments as the baseline.

15. During 2019/20, Heartflow, gammaCore, PLGF and SecurAcath were funded by the Innovation, Research, and Life Sciences (IRLS) Unit at NHS England. Payments were made directly from IRLS to suppliers. Therefore, they do not feature in the 2019/20 baseline provider income and were not incorporated in the emergency payments adopted in response to COVID-19. Unless the commissioner has amended the fixed payment in subsequent years to incorporate funding for MTFM supported technologies, any block contract payments issued in 2023/25 will not include MTFM technology or implementation costs.

Existing adopters of technologies

16. Some providers may have already adopted MTFM supported technologies. If this is the case, MTFM funding mechanisms should only be used if adoption has since ceased and implementation funding is required to reintroduce the technologies in the services offered, or additional funding is required to offer increased/improved patient access.

17. Implementation costs associated with adopting MTFM supported technologies or increasing their use should be incorporated in the fixed payment, with technology costs forming part of the variable element (as pass through payments based on technology cost and volume). If MTFM supported technology costs are included in the fixed payment, they should be removed and replaced with pass through payments based on the cost and volume of MTFM supported technology use.

Scenarios where MTFM funding mechanisms can be used

18. The three scenarios where MTFM funding mechanisms can be used are:

    A. a provider wants to embed one (or more) of the four 2021/22 MTFM supported technologies that it previously implemented

    B. a provider wants to implement an MTFM supported technology for the first time

    C. a provider wants to increase use of an MTFM supported technology that it has already adopted.

Scenario A: A provider wants to embed one or more of the four 2021/22 MTFM supported technologies

- If a provider implemented any of the four 2021/22 MTFM technologies during the ITP and now wants to make them business as usual (BAU), there will be no implementation costs, and technology costs will not be in the fixed payment baseline from 2019/20.
- Commissioners should pay for the relevant MedTech product(s) via pass through payments based on anticipated cost and volume.
- Commissioner and provider should agree a timeline for when the relevant MedTech product will be incorporated in BAU and passthrough payments will no longer be needed.

Embedding 2021/22 technologies

1. MedTech product costs not included in 2019/20 provider costs

2. Commissioners pay for MedTech product costs based on anticipated cost and volume
3. Supplementary cost of implementation included in fixed payment
4. Provider and commissioner agree timeline for incorporating MedTech in BAU

Scenario B: A provider wants to implement an MTFM supported technology for the first time

- Ensure the product and implementation costs were not included in the 2019/20 baseline.
- Identify implementation costs associated with introducing the technologies, in consultation with clinical and non-clinical colleagues with AHSN support.
- Understand how using the technology will release capacity and what setting/case mix of patients will be treated with this (released) capacity.
- Commissioners pay for the relevant MedTech product(s) via pass through payments based on anticipated cost and volume.
- Commissioner and provider agree a timeline for when the technology will be incorporated in BAU and become part of the fixed payment, and pass through payments will no longer be needed.

Implementing technologies for the first time

1. MedTech product costs not included in 2019/20 provider costs
2. Identify implementation costs
3. Commissioners pay for MedTech product costs based on anticipated cost and volume
4. Supplementary cost of implementation included in fixed payment
5. Provider and commissioner agree timeline for incorporating MedTech in BAU

Scenario C: A provider wants to increase usage of an MTFM supported technology that it has already adopted

- Agree any additional implementation costs with commissioner and anticipate the cost and volume of increased technology usage.
- Understand how using the technology will release capacity and what setting/case mix of patients will be treated with this (released) capacity.
- Commissioners pay for the relevant MedTech product(s) via either:

    a. agreeing further pass through payment based on anticipated cost and volume (and maintaining any pre-existing MTFM-related payments in fixed element)
    b. stripping any historical payment out of the fixed element and paying for all MTFM-related technology costs via pass through payments (to simplify funding flows).

- Commissioner and provider agree a timeline for when the relevant technologies will be incorporated in BAU and become part of the pass through payment, and pass through payments will no longer be needed.

Increasing usage of already adopted technologies

1. Some MedTech product costs included in 2019/20 provider costs
2. Understand how additional technology use will release capacity and how that will be used
3. Commissioners pay for MedTech product costs based on anticipated cost and volume
4. Supplementary cost of implementation included in fixed payment
5. Provider and commissioner agree timeline for incorporating MedTech in BAU

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Publication approval reference: PR00301