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MedTech Funding Mandate policy 2022/23

Guidance for NHS commissioners and providers of NHS-funded care

4 March 2022

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Foreword

In April 2021 the MedTech Funding Mandate (MTFM) policy was launched to support adoption of MedTech and diagnostic technologies across almost 200 healthcare services. This fulfilled a commitment in the NHS Long Term Plan to support commissioners and healthcare providers to bring life-changing innovations to patients quicker.

NHS England and NHS Improvement, the Academic Health Science Networks, National Institute for Health and Care Excellence (NICE) and NHS Supply Chain have worked with integrated care systems (ICSs) across England to help them implement the policy and manage the transition from central funding to commissioner funding for the four current technologies. This transition has largely been undisrupted by the pandemic, which is a testament to the commitment to make sure patients have access to the very best medical technologies.

Health systems are keen to adopt the new technologies and ensure that all eligible patients have access to them. For example, over the past year Alder Hey Children's Hospital, Royal Manchester Children's Hospital and Great Ormond Street Hospital have started to use SecurAcath, a device that secures peripherally inserted central catheters to allow children to resume normal activities between treatments.

Although it is too early to estimate the full impact of the MTFM policy, according to NICE resource impact assessments, the potential savings from its support of four technologies in 2021/22 are expected to be £25 million per year, compared to the cost of more traditional methodologies.

In its second year, effective from 1 April 2022, the MTFM policy is being expanded to include seven further technologies, across a variety of clinical conditions, with potential savings of £44 million. All the selected products enable high quality outcomes from treatment and depend on fewer resources, reducing theatre time and length of stay so that more patients across England can be treated quicker.

By supporting patients and providers to have equal access to transformative innovations and technologies, the policy aims to reduce health inequalities and improve equity of access for all and in particular those patients in disproportionately affected groups.

With this policy for 2022/23 we will continue to ensure eligible patients can have equitable access to the best new medical technologies faster.

Matthew Whitty

Mallos

Director of Innovation, Research and Life Sciences Chief Executive of the Accelerated Access Collaborative NHS England and NHS Improvement

Equality and health inequalities

- 1. Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement'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 by mandating access to their use through the funding mechanism across the whole of the NHS in England
 - ensuring our approach facilitates access by disproportionately affected groups
 - including technologies that treat conditions that disproportionately affect certain patient groups, such as 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 tells patients about the best treatments that their healthcare provider should be providing, supporting them to have informed discussions with their clinicians.

Introduction

6. In the NHS Long Term Plan, NHS England and NHS Improvement 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. This document updates the MTFM policy launched in April 2021, and is effective from 1 April 2022.

- 7. The <u>Life Sciences Vision</u> 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 quicker 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 Accelerated Access Collaborative (AAC)¹ innovation programmes, such as the Innovation and Technology Tariff/Payment programme (ITT/ITP),² 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 three 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. Since its launch, continued engagement has ensured that operational lessons learned from the MTFM policy's first year inform future policy development, improving the implementation experience.

¹ More information on the AAC is available here.

² More information on the ITT/ITP is available here.

- 12. 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 in 2022/23
 - iii. the implementation support available via NICE tools and resources, the Academic Health Science Networks (AHSNs) and NHS England and NHS **Improvement**
 - 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

- The MTFM policy is effective from 1 April 2022.
- 14. NHS England and NHS Improvement'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 and NHS Improvement will continue to consider technologies proven to be clinically effective and cost saving for inclusion in future 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.
- 15. Policy guidance will be reviewed in year to assess the impact of any legislative change arising from the Health and Care Bill.

Criteria for inclusion in the MedTech Funding Mandate 2022/23

16. The policy guidance for 2021/22 stated that the criteria for 2022/23 would change: namely, that the 2021/22's fifth criterion – previously supported through the ITT/ITP programmes – would be removed in 2022/23. Also, while the criterion for cost savings to be delivered within 12 months had the lowest support in the public consultation, it was retained for 2021/22 to ensure a focus on rapid return on investment while the NHS responds to the pandemic. This criterion has been changed to delivering savings within three years.

- 17. We reviewed the NICE medical technologies guidance (MTG) and NICE diagnostics guidance (DG) published by 30 June 2021 to identify devices, diagnostics or digital products that:
 - i. are effective: demonstrated through a positive NICE MTG or DG^{3,4}
 - ii. are cost saving within three years: NICE modelling demonstrates a net saving in the first three years of implementing the technology⁵
 - iii. are affordable to the NHS: the cost should not exceed £20 million in any of the first three years.6

2022/23 MedTech Funding Mandate technologies

- 18. The 2021/22 technologies will remain on the MTFM policy as long as they continue to meet the criteria set out at paragraph 17, supported by the published NICE guidance. The technologies supported in 2021/22 were:
 - placental growth factor-based testing (PIGF) (DG23)⁷ a diagnostic test to help rule out pre-eclampsia (Triage PIGF test and the Elecsys immunoassay sFlt-1/PIGF ratio)
 - SecurAcath (MTG34)⁸ for securing percutaneous catheters
 - **HeartFlow FFRCT (MTG32)** for estimating fractional flow reserve from coronary CT angiography
 - gammaCore (MTG46)9 a handheld device which alleviates the symptoms of severe cluster headaches by stimulating the vagus nerve.
- 19. With NICE, we will continue to monitor the spread, adoption and real world evidence from the implementation of these technologies, and compare this with NICE resource impact assessments (RIAs).

³ Information on MTGs and DGs can be found here.

⁴ 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; this process will be further developed in 2022.

⁵ Demonstrated by a NICE published resource impact assessment.

⁶ 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 three years.

⁷ NICE reviewed DG23 in February 2020 and recommended it is updated. This update is expected to be published on 20 July 2022. https://www.nice.org.uk/guidance/indevelopment/gid-dg10040

⁸ In January 2021, NICE started a review of MTG34. To register as a stakeholder, contact medtech@nice.org.uk

⁹ NICE will review MTG46 in 2022.

- 20. NICE guidance updates will be reviewed when published to understand changes to MTFM policy eligibility criteria.
- 21. Should either of the above assessments mean that a technology no longer meets the criteria for MTFM policy support, this finding will be communicated by publishing updated policy guidance.
- 22. The clinical standards section has been removed from the policy guidance for 2022/23. Please refer to the NICE guidance to access this information.
- 23. For all technologies supported under the MTFM policy, please refer to the NICE guidance to understand implementation eligibility.
- 24. For HeartFlow, the requirement for providers to perform at least 300 cardiac CT scans a year has been removed, allowing additional provider sites to adopt the technology where they have an eligible patient population.
- 25. Seven more technologies will be supported by the MTFM policy in 2022/23, selected by applying the criteria set out at paragraph 17.
- 26. Four technologies 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.
- 27. Three technologies 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 which accurately monitors and records air leak and fluid drainage.
- 28. Further detail on these technologies can be found in Annex 1.

- 29. All other technologies are funded by commissioners from existing allocations, except Spectra Optia.
- 30. 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 to six Clinical Reference Groups (CRGs), one of which is for haemoglobinopathies. These services are commissioned by NHS England. Therefore, Spectra Optia costs will be funded from existing NHS England allocations. The specific reimbursement methodology is still to be finalised.

Communication of future changes to MTFM policy criteria and products

- 31. The MTFM policy will be published annually, following a guidance review and feedback improvement cycle, and will become effective on 1 April the following year.
- 32. NICE MTGs and DGs will be reviewed through the year prior to the updated MTFM policy becoming effective, and a list of technologies that meet the MTFM criteria will be published on the AAC webpages.
- 33. 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 MTFM policy webpage.
- 34. Removal of technologies will be signalled in year via the webpage giving commissioners and providers who may be impacted by the change time to prepare.
- 35. Changes are also to be referenced in the annual NHS operational planning and contracting guidance.
- 36. The technologies covered by the MTFM policy will be updated annually in related NHS England and NHS Improvement publications, including the National Tariff Payment System (NTPS) and NHS Standard Contract. These are typically published on the NHS England and NHS Improvement website between December and March and are subject to their own consultation processes.

- 37. 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".
- 38. The MTFM policy will be updated in line with any relevant and significant legislative changes.
- 39. 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 here and search for the MTFM workspace to request membership.

NHS payment system

Financial impact

- 40. 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 three years (see criteria for inclusion) as estimated by NICE RIAs.
- 41. The NICE RIAs for the seven technologies that meet the criteria for 2022/23 estimate that:
 - · without implementation or continuation of use of these technologies, the cost of care would be around £498 million over five years
 - by implementing them, the cost of care reduces to £454 million over five years. Implementation would therefore achieve a net saving to the taxpayer of around £44 million over five years.
- 42. The savings analysis from NICE can be found in Annex 2.
- 43. NICE also produces tools to help providers and commissioners understand the impact on their patient population; see Annex 1.

Innovation payment policy development

- 44. NHS England and NHS Improvement have identified payment and non-payment barriers to adoption and spread of innovation, and developed solutions to address these, including a new payment policy proposal and implementation guidance for the 2022/23 payment cycle.
- 45. Following engagement with clinicians, providers and commissioners, it has been proposed that payment for technologies should initially be excluded from the Aligned Payment and Incentive (API) policy.
- 46. The policy development addresses the issues experienced in 2021/22.
- 47. The intended reimbursement mechanism for 2021/22 was for commissioners to reimburse providers for the cost of the technologies, in addition to tariffs known as 'pass through' payments.
- 48. Due to COVID-19, the NTPS for 2021/22 was paused and system funding envelopes, comprising adjusted clinical commissioning group (CCG) allocations, system top-up and COVID-19 fixed allocation, and policy priorities were put in place.
- 49. Consequently, providers and commissioners approached the policy as an API¹⁰ and found it difficult to navigate. Feedback from the sector was that this meant funding for MTFM technologies was either delayed or not approved.
- 50. The MTFM guidance in 2021/22 gave background information on blended payments. For 2022/23, API is the defined approach for blended payments.

Funding the cost of the technologies

51. For 2022/23 the MTFM policy therefore continues to take 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 will be excluded from the national prices with a list of technologies published in the tariff workbook (Annex A), on an 'innovative products' tab. 11

¹⁰ Providers and commissioners should refer to the NHS payment system for rules and guidance on API

¹¹ Changes to NHS payment processes may be required in 2022/23 in response to the ongoing pandemic.

- 52. Items on the innovative products list are subject to NTPS 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 and NHS Improvement, whichever is the lowest.
- 53. For 2022/23 NHS England and NHS Improvement will not set any reference prices for the technologies supported; therefore, actual cost to providers should be reimbursed by commissioners.
- 54. The purchase of a new Spectra Optia apheresis machine will be a capital purchase and should be added by providers to their priority capital spend list. On the completion and approval of a business case, the depreciation will be reimbursed by the NHS England Specialised Commissioning devices programme¹².

Funding the cost of implementation

- 55. Pass through payment for the technologies does not include implementation or running costs: this was highlighted as a barrier to adoption. Therefore, as part of the NHS payment system consultation, 13 the payment policy proposes that the API fixed payment between commissioners and providers is adjusted accordingly for these costs in 2022/23.
- 56. 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

- 57. The NHS England and NHS Improvement innovation payment project is developing guidance to help commissioners and providers navigate the payment system for 2022/23. Providers and commissioners need to understand both the 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.¹⁴
- 58. NICE provides tools and resources as part of the published MTG or DG guidance to help with this. NHS England and NHS Improvement, the AHSNs and technology

¹² Exact details to be finalised.

¹³ The latest tariff development information can be found <u>here</u>.

¹⁴ Financial processes may be impacted in 2022/23 by pandemic response financial guidance, so are subject to change.

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 2022

- 59. The 2022 National Cost Collection will include cost and activity data for the technologies supported in the 2021/22 MTFM policy.
- 60. The four technologies supported in 2021/22 were all centrally funded by the ITP programme, with payments 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 their costs are now known and can be included in local service-line reporting (SLR) information ¹⁵ and in the National Cost Collection data in 2022.
- 61. For the National Cost Collection in 2022, NHS England and NHS Improvement have added a new functionality to the integrated technical document to enable providers to identify the technologies supported by the MTFM policy in their cost data.
- 62. Also, NHS provider costing practitioners should use a new collection resource code to identify the cost of the technologies supported by the MTFM policy in their submissions. This code will enable NHS England and NHS Improvement 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.¹⁶
- 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 MTFM policy.

¹⁵ SLR is not mandated and frequency of reporting is locally determined. Contact your provider's costing teams for more information.

¹⁶ https://feedback.model.nhs.uk/knowledgebase/articles/1123735-introduction-to-the-model-healthsystem

Procurement of MTFM technologies

- 64. During engagement events, both providers and commissioners proposed using the NHS England Specialised High Cost Tariff Excluded Devices (HCTED) programme using the NHS Supply Chain procurement route to enable easier reimbursement of pass through payments for technologies. All stakeholders agreed this is the best option for the MTFM policy.
- 65. Technologies included in the MTFM policy should be procured through the relevant NHS Supply Chain framework; procurement should not be individually negotiated with suppliers.
- 66. At the time of publication, NHS England and NHS Improvement are working with NHS Supply Chain and a phased approach will be required. Updated guidance will be issued and any developments will be communicated on the MTFM policy webpage and the Future NHS page.
- 67. Once technologies are moved onto the new reporting framework, commissioners will receive a monthly report from NHS England detailing the products purchased via the central procurement route for providers within their system. This should be used by commissioners as the basis for reimbursement for each provider. The provider will also receive a copy as part of the HCTED process.
- 68. It will be the commissioner's responsibility to reimburse the providers for the MTFM technologies.
- 69. It will be the provider's responsibility to ensure they are purchasing through NHS Supply Chain, or reimbursement will not be actioned.
- 70. Providers of NHS-funded services can set up an NHS Supply Chain account here.
- 71. Non-NHS providers of NHS-funded services can apply for an NHS Supply Chain account here.
- 72. Detailed step-by-step guidance for ordering via the NHS Supply Chain online catalogue is available here.

Performance and evaluation

Spread and adoption of MTFM technologies

- 73. NHS England and NHS Improvement 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 AAC scorecard, which is published on FutureNHS¹⁷ and is used to demonstrate the stage of adoption each provider is at for each MTFM technology.
- 74. The reporting identifies which providers and commissioners have yet to adopt technologies, supporting discussion on barriers and helping them learn from other providers and commissioners that have successfully adopted.
- 75. NHS England and NHS Improvement are also working with the Model Health System to develop a new innovation opportunity dashboard. Providers and commissioners will be able to access this to see which integrated care systems have implemented the MTFM technologies and the patient and system outcomes from doing so.

Monitoring compliance

- 76. The 2022/23 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.
- 77. This would not be required where the NICE recommendations are not relevant to the organisation (e.g. the provider does not provide services for the specific patient cohort the technology supports, or an alternative treatment is more appropriate for these patients).
- 78. 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.

¹⁷ Access to the AAC scorecard dashboard on FutureNHS can be requested here.

- 79. 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, provider organisations may wish to review how they demonstrate their compliance with the MTFM.
- 80. Examples of how NHS commissioners and providers of NHS-funded services can evidence compliance with MTFM policy guidance include:
 - i. ICSs 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.
- 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 AAC scorecard and monitored through the AAC board. 18 When NHS England and NHS Improvement are made aware of non-compliance through NHS Supply Chain and AHSN QART data, we will seek to engage with the relevant providers and commissioners to provide support, and understand barriers and how to overcome these. This will ensure the MTFM policy aim of equitable health access across England is achieved.

Implementation support

Academic Health Science Networks

- 82. Providers of NHS-funded services and NHS commissioners have access to implementation support from the 15 AHSNs across England.
- 83. NHS England established the AHSNs in 2013 to spread innovation, improve health and generate economic growth. Each AHSN works across a distinct geography

¹⁸ Further details about the AAC can be found here.

- serving a different population in each region and is connected to the regional and local NHS structures.
- 84. 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. 19
- 85. 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.
- 86. 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.
- 87. To contact your local AHSN for support, please visit this webpage.

NICE tools and resources

- 88. 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 quidance
 - 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, 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.

¹⁹ https://www.ahsnnetwork.com/

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

Roles and responsibilities

- 90. This section describes the roles and key responsibilities for various MTFM policy stakeholders including:
 - suppliers of technologies included on the policy
 - NHS England and NHS Improvement
 - AHSN technology leads
 - individual AHSNs
 - NHS providers corporate teams
 - NHS providers clinical teams
 - NHS commissioners (ICSs).²⁰

Suppliers of technologies supported by the MedTech Funding Mandate

- 91. 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 about 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

²⁰ Policy guidance will be reviewed in year to assess the impact on key stakeholders of any legislative change arising from the Health and Care Bill.

included in the MTFM policy is not a sales opportunity: the focus is equitable patient access.

NHS England and NHS Improvement

- 92. NHS England and NHS Improvement are expected to:
 - engage with NICE, AHSNs, Supply Chain Coordination Ltd (SCCL) and NHS Supply Chain²¹ to develop and improve MTFM policy documents and operational processes
 - produce MTFM policy documents, tools and engagement pieces, including for patient and public involvement
 - prepare AHSN leads and suppliers for 1 April 2022 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

- 93. 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 to overcome clinical barriers to adoption by offering advice and guidance to all AHSNs, working with clinical champions where appropriate
 - work with NHS England and NHS Improvement to develop case studies and deliver engagement pieces, including webinars, to support implementation and spread

²¹ SCCL is the management function for the NHS Supply Chain operating model.

 report national progress to the AHSN National Programme Director to support governance processes.

Individual AHSNs

94. 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 from across the AHSN network (the collective of all 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

95. 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 provide²²
- engage with NHS England and NHS Improvement national payment system 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

²² Information in the NICE guidance together with the tools and resources will assist.

- 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 Futures²³ NHS workspace to be aware of any planned engagement events and policy developments.

NHS providers – clinical teams

96. 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 guidance²⁴
- 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 in 2022/23
- promote service improvements with primary care services
- record outcomes and benefits data achieved through technologies and share appropriately
- join the MTFM Futures NHS workspace, which provides updates on planned engagement events and policy developments.

NHS commissioners (ICSs)

97. NHS commissioners (ICSs) are expected to:

- familiarise themselves with the MTFM policy guidance
- engage with NHS England and NHS Improvement national payment system guidance, tools and communications that support the MTFM policy
- identify local patient populations that technologies will benefit (using NICE) resource impact templates)

²³ Once you have access to FutureNHS, you will find the MTFM page.

²⁴ Links to the NICE guidance are given in Annex 1.

- engage with providers to agree projected activity and how this fits 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 Futures NHS workspace, which provides updates on planned engagement events and policy developments.

Annex 1: Innovations supported by the MedTech Funding Mandate from 1 April 2022

NICE reference	Description of innovation	Clinical benefit (as stated by NICE)	Patient benefit (as stated by NICE)	Link to NICE guidance and product website
MTG32 HeartFlow	HeartFlow FFRCT estimates fractional flow reserve from coronary CT angiography (CCTA) for patients with stable, recent-onset chest pain.	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.	 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. 	 https://www.nice. org.uk/guidance/ mtg32 https://www.heart flow.com/
MTG34 SecurAcath	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).	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.		https://www.nice. org.uk/guidance/ mtg34 https://securacat h.com/
MTG46 gammaCore	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.	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	 Significant quality of life improvement from reduced pain during an attack. Reduced need for expensive medication. Reduced hospital visits. 	 https://www.nice. org.uk/guidance/ mtg46 https://www.gam macore.com/

NICE reference	Description of innovation	Clinical benefit (as stated by NICE)	Patient benefit (as stated by NICE)	Link to NICE guidance and product website
		improve quality of life for people living with this condition.		
DG23 PIGF	Placental growth factor (PIGF)-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.	Using PIGF-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 PIGF-based test to return to community care instead of being admitted to hospital for observation.	 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. 	https://www.nice. org.uk/guidance/ dg23 https://diagnostic s.roche.com/glob al/en/products/pa rams/elecsys- sflt-1-plgf- preeclampsia.ht ml https://www.quid el.com/immunoa ssays/triage-test- kits/triage-plgf- test
MTG58 UroLift	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 performed under local anaesthesia in an outpatient setting or ambulatory care centre, and the patient can return home the same day without a catheter.	UroLift relieves lower urinary tract symptoms for up to five years. It also improves quality of life and avoids risk to sexual function.	 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 done without an overnight stay in hospital, allowing the patient to return home without a urinary catheter. 	https://www.nice. org.uk/guidance/ mtg58 https://www.urolif t.com/
MTG29 GreenLight XPS	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	GreenLight XPS uses a laser to reduce the size of an enlarged prostate, easing the symptoms of benign prostatic hyperplasia (BPH).	 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. 	https://www.nice. org.uk/guidance/ mtg29 https://www.bost onscientific.com/ en-EU/health- conditions/enlarg ed-prostate/our- treatments/green

NICE reference	Description of innovation	Clinical benefit (as stated by NICE)	Patient benefit (as stated by NICE)	Link to NICE guidance and product website
	risk of complications and allows a quicker return to normal activity.			Light-laser- therapy.html
MTG49 Rezum	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.	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.	 Relieves symptoms. Improves quality of life. Minimally invasive, which means open surgery is not needed. Unlikely to need a stay overnight in hospital. 	https://www.nice. org.uk/guidance/ mtg49 https://www.bost onscientific.com/ en- US/products/litho tripsy/rezum- water-vapor- therapy.html
MTG53 PLASMA System	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 the need for blood transfusion.	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 less chance of serious complications.	 Less chance of serious complications. Reduces the length of hospital stay. This procedure can be done as a day case. 	https://www.nice. org.uk/guidance/ mtg53 https://www.olym pus.co.uk/medic al/en/Products- and- solutions/Product s/Product/PLAS MA- SYSTEM.html
MTG30 XprESS multi-sinus dilation system	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	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	 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. 	 https://www.nice. org.uk/guidance/ mtg30 https://www.stryk er.com/gb/en/ent /products/xpress. html

NICE reference	Description of innovation	Clinical benefit (as stated by NICE)	Patient benefit (as stated by NICE)	Link to NICE guidance and product website
	endoscopic sinus surgery (FESS) procedures.	the NHS. As such, it may improve quality of life and clinical outcomes, as well as reduce surgical waiting lists.		
MTG37 Thopaz+ portable digital system	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.	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.	 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+. 	https://www.nice. org.uk/guidance/ mtg37 https://www.med elahealthcare.co m/en- GB/solutions/che st- drainage/thopaz
MTG28 Spectra Optia	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.	Faster and needs to be done less often than manual red blood cell exchange.	Faster and needs to be done less often than manual red blood cell exchange.	https://www.nice. org.uk/guidance/ mtg28 https://www.teru mobct.com/spect ra-optia

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

Product	Guidance	Estimated cost of current practice	Estimated cost of future practice (Y5)	Resource impact (Y5)
		£	£	£
HeartFlow	https://www.nice.org.uk/guidance/mtg32/resources/resource- impact-template-excel-4363976701	67,155,804	64,677,299	2,478,504
SecurAcath	https://www.nice.org.uk/guidance/mtg34/resources/resource- impact-template-excel-10947880909	5,345,157	2,799,535	2,545,622
PIGF	https://www.nice.org.uk/guidance/dg23/resources/resource- impact-template-excel-2484575821	22,193,000	17,926,527	4,266,473
gammaCore	https://www.nice.org.uk/guidance/mtg46/resources/resource- impact-template-excel-7078045645	216,891,554	214,089,845	2,801,709
Greenlight	https://www.nice.org.uk/guidance/mtg29/resources/resource-impact-template-excel-10948168621			
Rezum PLASMA system	https://www.nice.org.uk/guidance/mtg49/resources/resource-impact-template-excel-10948168621 https://www.nice.org.uk/guidance/mtg53/resources/resource-impact-template-excel-10948168621	80,184,845	68,095,210	12,089,636
Urolift	https://www.nice.org.uk/guidance/mtg58/resources/resource- impact-template-excel-10948168621			
Xpress	https://www.nice.org.uk/guidance/mtg34/resources/resource-impact-template-excel-10947880909	21,752,425	16,221,856	5,530,569

Product	Guidance	Estimated cost of current practice	Estimated cost of future practice (Y5)	Resource impact (Y5)
		£	£	£
Thopaz	https://www.nice.org.uk/guidance/mtg37/resources/resource- impact-template-excel-4787145325	57,798,050	48,183,361	9,614,689
Spectra Optia	https://www.nice.org.uk/guidance/mtg28/resources/resource-impact-template-excel-10948023469	27,156,262	22,036,283	5,119,980
Total		498,477,097	454,029,916	44,447,181

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