Classification: Official

MedTech Funding Mandate policy 2021/22

Guidance for NHS commissioners and providers of NHS-funded care

January 2021

Contents

Foreword

I am delighted to be launching the MedTech Funding Mandate policy to support commissioners and providers to use clinically effective and cost-saving medical devices, diagnostics and digital technologies that will improve patient outcomes. This policy will benefit patients by enabling faster and wider sustainable adoption of proven and affordable innovations, a commitment in The NHS Long Term Plan.

COVID-19 has impacted all of our lives and been the greatest challenge to the NHS in generations. The response to COVID-19 delayed the previous launch of the MedTech Funding Mandate, but the response has also taught us that we now can't lose the opportunity to embed positive changes and we should continue to build on our collaborative working and strength our partnerships across the health system. The MedTech Funding Mandate underscores the importance of companies working with NICE to put their technologies through the appropriate assessments. NHS England and NHS Improvement will consider technologies proven to be clinically and cost-effective for inclusion in the future updates of the policy.

We look forward to working with you to implement the MedTech Funding Mandate to make sure the best medical technologies get to patients faster.

I want to thank all those who have been involved in the development of the MedTech Funding Mandate; in particular the specialist procurement teams, commissioners, regulators, clinical providers, technology suppliers and other colleagues across NHS England and NHS Improvement, as well as all those who responded to the public consultation.

Matthew Whitty

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

Equality and health inequalities statement

Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Introduction

1. In the NHS Long Term Plan, NHS England and NHS Improvement outlined how research and innovation would drive better outcomes and experience for patients.[1] An important element of this was the commitment to introduce a MedTech Funding Mandate 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 faster.

2. This MedTech Funding Mandate policy builds on the priorities of the Accelerated Access Collaborative (AAC)[2] innovation programmes, such as the Innovation and Technology Tariff/Payment programme (ITT/ITP),[3] introduced to address financial and procurement barriers to the adoption of devices, diagnostics and digital products.

3. The aims of the policy are to:

   i) direct the NHS on which MedTech innovations are effective and likely to give savings on investment;

   ii) ensure the NHS has a sustainable approach to overcoming the financial barriers to adopting medical devices, diagnostics and digital products.

4. Following public consultation in December 2019,[4] we committed to launch the MedTech Funding Mandate, to come into effect in April 2020.

5. Launch was delayed because the mandate is supported by both the NHS Standard Contract and the National Tariff Payment System (NTPS), the development of which for the next financial year was suspended owing to the COVID-19 pandemic. The development work continued throughout the year for inclusion in the next iterations of these documents. Following engagement with internal and external stakeholders, the MedTech Funding Mandate policy ('the policy') will take effect from 1 April 2021.

[1] See paragraph 3.112-3.120 of The NHS Long term Plan.
[2] More information on about AAC is available here.
[3] More information on about the ITT/ITP is available here.
[4] https://www.engage.england.nhs.uk/consultation/medtech-funding-mandate/

6. This policy is for NHS providers and their commissioners in England and explains:

   i) the scope of the MedTech Funding Mandate

   ii) which technologies are included in 2021/22 and the clinical standards required for their adoption

   iii) the implementation support available via NICE tools and resources, via the Academic Health Science Network and the continuing work of the AAC team to support this policy development

   iv) the steps NHS providers, NHS commissioners and suppliers of technologies need to take and how they will be supported by the policy and the academic health science networks

   v) plans for reporting activity and compliance monitoring

   vi) plans for 2022 onwards.

Scope

8. The policy is effective from 1 April 2021.

9. The MedTech Funding Mandate is an NHS Long Term Plan commitment to give patients access to selected NICE-approved cost-saving devices, diagnostics and digital products more quickly.

10. The AAC team is responsible for identifying innovations for the policy, supported by input 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.

Criteria for inclusion in the MedTech Funding Mandate 2021/22

11. We reviewed all NICE medical technologies guidance (MTGs) and NICE diagnostics guidance (DGs) published by 30 June 2020 to identify devices, diagnostics or digital products that:

    i) **are effective:** demonstrated through a positive NICE MTG or DG;[5]

    ii) **deliver material savings to the NHS:** the benefits of the innovation are over £1 million over five years for the population of England;

    iii) **are cost-saving in-year:** NICE modelling demonstrates a net saving in the first 12 months of implementing the technology;

    iv) **are affordable to the NHS**: the budget impact should not exceed £20 million, in any of the first three years.[6]

12. To ensure that the adoption of this policy does not create undue burden on providers and commissioners, it is being launched in 2021/22 with a small number of products that meet the criteria above, and a fifth criterion that the products were previously supported through the ITT/ITP programmes.[7]

[5] More information on MTGs and DGs can be found here.
[6] We reserve the right to not include a technology in the MedTech Funding Mandate 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] More information on about the ITT/ITP is available here.

13. This fifth criterion will be in place for the first year of the MedTech Funding Mandate policy only.

14. The criterion for cost savings to be delivered within 12 months had the lowest support in the public consultation but has been retained for 2021/22 to ensure a focus on rapid return on investment while the NHS responds to the pandemic.

2021/22 MedTech Funding Mandate technologies

15. The technologies that meet the five criteria are:

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

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

Criteria for inclusion on the MedTech Funding Mandate from 1 April 2022

17. From 1 April 2022 technologies not previously supported by ITT/ITP may be covered by the MedTech Funding Mandate.

18. Increasing the time over which technologies can demonstrate savings to beyond 12 months can allow more effective NHS organisational planning and, recognising the lower level of support for this criterion, the criterion will change as soon as possible. From the second year of the policy, from 1 April 2022, technologies will need to demonstrate a net saving across a three-year period.

19. Technologies that have their MTG or DG published up to and including the 30 June 2021 will be reviewed to identify any devices, diagnostics or digital products that:

i) are effective: demonstrated through a positive NICE MTGs or DGs;[8]

ii) are cost-saving **within three years**: NICE modelling[9] demonstrates a net saving in the first three years of implementing the technology; and

iii) are affordable to the NHS: the budget impact should not exceed £20 million in any of the first three years[10].

Communication of future changes to policy criteria and products

20. The MedTech Funding Mandate policy will be published annually in December following a review and feedback improvement cycle which will become effective on 1 April the following year.

21. NICE MTGs and DGs will be reviewed through the year prior to the updated policy becoming effective, and a list of technologies that meet the MedTech Funding Mandate criteria will be published on the AAC webpage (in the signalling document) before end of July alongside with accompanying support to providers to help adopt these technologies as soon as possible.

22. The technologies already covered by the policy will be reviewed 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 will be withdrawn this will be signalled ahead of further policy publication.

23. By publishing the technologies which meet the criteria for the MedTech Funding Mandate for the following year in the signalling document each July we will:

    i) support more patients benefitting by enabling NHS organisations who want to use these technologies sooner to have earlier conversations about how to implement them;

[8] More information on MTGs and DGs can be found here.
[9] Published in a NICE resource impact template
[10] we reserve the right to not include a technology in the MedTech Funding Mandate and / or to undertake further commercial negotiations with manufacturers if we believe the £20m cost limit will be exceeded in any of the first 3 years

ii) provide implementation support for NHS organisations that wish to adopt these technologies in year, ahead of the contractual requirement; and

iii) allow more time for discussion with industry on what implementation approaches are likely to be needed for these technologies

24. Changes will also be referenced in the annual NHS Operational Planning and Contracting Guidance[11].

25. The technologies covered by the MedTech Funding Mandate 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.

26. The MedTech Funding Mandate will also be updated in line with any relevant and significant legislative changes.

27. The publication cycle for the MedTech Funding Mandate policy and the associated signalling documents is shown in Table 1.

Table 1: Policy document publication schedule for 2021/22 to 2023/24

Document	Publication date*
MedTech Funding Mandate policy for 2021/22	January 2021
MedTech Funding Mandate signalling document for 2022/23	July 2021
MedTech Funding Mandate policy for 2022/23	December 2021
MedTech Funding Mandate signalling document for 2023/24	July 2022
MedTech Funding Mandate policy for 2023/24	December 2022

*** Publishing dates and document titles are subject to change.**

[11] https://www.england.nhs.uk/operational-planning-and-contracting/

National Tariff Payment System

Financial impact

28. One of the criteria for 2021/22 ensures that the technologies selected are cost-saving within 12 months (see paragraph 11), as estimated by NICE resource impact template.

29. The NICE resource impact templates for the four technologies that meet the criteria for 2021/22 estimate that:

    i) without implementation or continuation of use of these technologies, the cost of care would be around £323 million over five years;

    ii) by implementing them, the cost of care reduces to £298 million over five years. Implementation would therefore achieve a net saving to the taxpayer of around £25 million over five years.

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

31. NICE also produces tools to help providers and commissioners understand the impact on their patient population shown in Annex 1.

Funding of Technologies

32. To date, NHS England and NHS Improvement have funded the cost of procuring products on the ITT/ITP programmes which have been funded directly by directly reimbursing the supplier.

33. The MedTech Funding Mandate does not directly fund the technologies included in the policy. NHS-funded care providers are to be reimbursed by their commissioner.

34. Annex A of the NTPS lists the technologies in the MedTech Funding Mandate policy, called the innovative products list. Items on this list are excluded from national prices and reimbursed by NHS commissioners.

35. Items on the innovative products list are subject to NTPS local pricing rule 5, 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.

36. The innovative products list will be reviewed as part of developing the proposals for the 2021/22 NTPS.

Blended payments

37. The NHS Long Term Plan committed to moving away from activity-based funding and making almost all funding population-based. This would involve moving to blended payment for almost all services.

38. Our Pricing team carried out initial engagement on the future direction of the NTPS, proposing a move away from activity-based payments from 2021/22. If introduced, this would signal a move to blended payment arrangements for almost all activity, above a threshold contract value. The blended payment arrangements would be largely based on a fixed payment conforming to integrated care system plans.

39. The design of the blended payment model is under development and will be subject to statutory consultation before introduction. One of the principles under consideration is that any funding arrangement between a commissioner and provider should be included in the fixed payment unless there is justification for exemption.

40. For the MedTech Funding Mandate, this would have impact in the first year of implementation: for any technologies supported by the policy, the activity and cost would be agreed between providers and commissioners and added to the fixed payment. This would enable providers to understand their levels of funding upfront, to aid planning.

41. Where activity levels are hard to predict, adding the cost to the fixed payment may be considered too difficult. In this situation, a ‘risk share’ agreement could be considered (see the next section), such as those often used for high-cost devices or high-cost drugs.

Risk share agreements

42. Implementing the MedTech Funding Mandate requires an understanding of how the technologies would be used in both current and future care pathways.

43. It also requires an understanding of the potential risks and rewards the innovations may bring to both providers and commissioners, considered together as part of planning and implementing changes at a system level.

44. As it is hard to know in advance exactly what the impact of any changes will be, a risk share can be used to even out any imbalance in costs and savings between organisations to encourage implementation.

45. Risk sharing can be broadly be defined in two ways:

    i) appropriately distributing risk between parties when the risks and rewards of an action are based in separate areas

    ii) pre-agreed mechanisms to redistribute resources in response to variations from plan.

46. If only one organisation is involved in the innovative care pathway, then a risk share is unlikely to be needed.

47. If more than one organisation is involved, alignment between providers and commissioners may be challenging. A number of potential risk-sharing options could mitigate risk of cost and reward in different areas. There are six main areas to consider:

    i) **Risk pool** – this risk is where more than two organisations are involved. The main risk is system buy in and accountability due to the need for multiple agreements;

    ii) **Cost and benefit redistribution** – this risk is where one provider bears the cost of the technology, but the benefits are realised by another provider, e.g. where an NHS trust provides technology that reduces the need for community nurse visits;

    iii) **Risk share attached to inputs** – this risk is where the implementation input, such as training cost, is a burden on one provider, but another

provider also sees savings. The agreement shares the implementation cost;

iv) **Income guarantee** – this risk is where the technology reduces provider income by reducing the number of attendances needed or avoids the need for surgical interventions;

v) **Time delay** – this risk arises when the benefits of the technology are not realised within the same period as the cost;

vi) **Variation from plan** – this risk is where a technology is new it may cause an unplanned deviation from the planned level of activity.

48. The NHS England and NHS Improvement Pricing team are developing a collaboration work platform to share educational tools for the management of risk sharing. We will share the details access details when it has been launched.

Procurement

49. Technologies in the MedTech Funding Mandate can be procured through the relevant NHS Supply Chain framework from 1 April 2021. This gives providers the option of procuring them through this framework rather than doing so themselves.

50. Providers of NHS-funded services can set up an NHS Supply Chain account here.

51. Non-NHS providers of NHS-funded services can apply for an NHS Supply Chain account here.

52. Detailed step-by-step guidance for ordering via the NHS Supply Chain online catalogue is available here.

Reporting of activity and costs

Legacy ITT/ITP reporting

53. Technologies in the MedTech Funding Mandate in 2021/22 were previously funded by the ITT/ITP programmes. When funding responsibility for technologies transfers to local NHS commissioners on 1 April 2021, the collection of uptake data via the ITT/ITP programmes will cease.

National Cost Collection

54. From 1 April 2021 the cost of the technologies purchased will flow through providers accounting systems and be included in provider's local service-line reporting (SLR) information[12] and in the annual National Cost Collection data in 2022.[13]

55. We are working with the Costing team and propose the formation of a Costing Expert Working Group for Innovation. Membership would include costing practitioners from NHS providers to work with the Costing team and AAC to ensure the costing standards[14] incorporate the technologies in the MedTech Funding Mandate.

56. We will also work with the Costing team to understand how the use of technologies will be identified at patient level in the National Cost Collection. This information will enable local and national analysis to demonstrate the cash-releasing and non-cash releasing benefits from adopting the technologies in the policy.

57. Further information on the progression of this work will be available in the FAQ document which will be published alongside this policy on the AAC MedTech Funding Mandate webpage[15].

[12] SLR is not mandated and frequency of reporting is locally determined. Contact your provider's costing teams for more information
[13] https://www.england.nhs.uk/national-cost-collection/
[14] https://www.england.nhs.uk/approved-costing-guidance-2020/
[15] https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/the-medtech-funding-mandate/

Monitoring compliance

58. The NHS Standard Contract[16] 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.[17]

59. Compliance would not be relevant where, for example:

    i) the NICE recommendations are not relevant to the organisation (e.g. a provider does not provide services to the specific patient cohort the technology supports);

    ii) individual patient clinical history and current presentation mean that another treatment is better suited to that patient.

60. Technologies included in the MedTech Funding Mandate have been proven to support safe and effective care and this can be evidenced as part of a Care Quality Commission (CQC) inspection.

61. Together with the strengthened NHS Standard Contract requirement to comply with the MedTech Funding Mandate, 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 MedTech Funding Mandate.

62. Examples of how NHS commissioners and providers of NHS-funded services can evidence compliance with MedTech Funding Mandate policy guidance include:

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

[16] https://www.england.nhs.uk/nhs-standard-contract/21-22/
[17] https://www.england.nhs.uk/nhs-standard-contract/20-21/

ii) Providers of NHS-funded services publishing their policies and clinical care pathways to demonstrate that innovations covered by the MedTech Funding Mandate are available and evidence these 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 MedTech Funding Mandate.

63. We will continue to work with the product suppliers and NHS Supply Chain to track the uptake of the technologies covered by the MedTech Funding Mandate. Uptake data will be included in the AAC scorecard and monitored through the AAC board.[18]

[18] Further details about the AAC can be found here

Adoption and implementation support

NICE tools and resources

64. 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, including:

    - 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.

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

Academic health science networks

66. Providers of NHS-funded services and NHS commissioners also have access to implementation support from the 15 academic health science networks (AHSNs) across England.

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

68. 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]

69. The AHSN network has extensive experience of implementing these technologies in the NHS, having supported the national implementation and adoption part of the ITT/ITP programmes.

70. 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.

71. To contact your local AHSN for support please visit its website.[20]

Accelerated Access Collaborative team

72. The AAC team are working closely with the technology suppliers and the national AHSN product leads.

73. A joint-working group has been established to address issues raised, share learning and offer possible solutions to barriers faced when implementing the MedTech Funding Mandate policy.

74. Providers and commissioners will be able to raise queries with this group, and the AAC team will aim to log, action and resolve these. All queries should be raised with the AHSNs in the first instance, and they will escalate them to the AAC if necessary.

75. Any commonly identified challenges or issues will be published alongside this guidance on the AAC web page[21] and used to support the further development of this policy.

[19] https://www.ahsnnetwork.com/
[20] https://www.ahsnnetwork.com/contact-the-ahsn-network

[21] https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/the-medtech-funding-mandate/

Next steps

76. Organisations will want to prepare to apply the MedTech Funding Mandate policy. This section describes the actions required to transition from ITT/ITP to the MedTech Funding Mandate and how to demonstrate compliance with the policy, with information for:

- NHS providers
- NHS commissioners
- Suppliers of technologies supported by the MedTech Funding Mandate
- AHSNs.

NHS providers

77. NHS providers will need to understand which technologies they have implemented under ITP and which they will need to adopt with the support of the MedTech Funding Mandate and agree how they will do this locally. Next steps may include:

i) Identify the products supported by the MedTech Funding Mandate in 2021/22 that are relevant to the services you provide;

ii) Understand the benefits those technologies bring to both patients and clinicians and how their implementation will change current patient pathways (engage with your local AHSN);

iii) Engage with your local AHSN for further information on the evidence base for the use of the product or extra implementation support;

iv) Understand current and projected level of technology uptake, and review the organisational change required and plans for this;

v) Agree the expected level of activity for each technology in 2021/22;

vi) Make provision for payment flows changing when ITT/ITP support ends on 31 March 2021: agree local processes with commissioners to implement these technologies;

vii) Engage your commissioning (usually in finance) and costing teams to plan your current and future contracting arrangements.

NHS commissioners

78. NHS commissioners are key to driving innovation and ensuring that patients have access to the proven, cost-saving technologies that are supported by the MedTech Funding Mandate, by explaining the impact of the technology to providers and supporting them in planning conversations.

79. Below are the steps that commissioners can take to help providers and suppliers' transition from the ITP programme to the MedTech Funding Mandate policy:

    i) Become familiar with of the technologies supported by the MedTech Funding Mandate policy and how they can benefit patients by reducing admissions, length of stay and/or prescribing, and avoiding clinical intervention;

    ii) Identify the patient population in your locality who could benefit from the technologies using the tools created by NICE and understand the budget impact implementation will have for your providers;

    iii) Engage with communications from and events held by our NTPS team and the AAC, to understand payment system developments which support the funding of the use of technologies in the MedTech Funding Mandate policy;

    iv) Engage with your providers on the MedTech Funding Mandate policy and the technologies it supports, to agree the projected activity and how this fits in with current and future contractual arrangements.

Suppliers of technologies supported by the MedTech Funding Mandate policy

84. Companies supplying the technologies included in the first year of the policy will lead the way for future innovators: learning from their experience will support future iterations of the policy.

85. Next steps for suppliers may include:

i) Work with the national AHSN product lead and local AHSN to understand the provider–commissioner landscape and the national implementation status of the technology;

ii) Collaborate with the national AHSN product lead and local AHSN to complete the MedTech Funding Mandate tracker provided by NHS England and NHS Improvement;

iii) Understand the next steps for providers, as given in this policy, and work closely with the national AHSN product lead and local AHSN to support engagement;

iv) Support clinicians in their discussions with operational managers and finance colleagues;

v) Develop location-specific business cases for funding, noting local arrangements.

vi) Attend NHS England and NHS Improvement action learning sets with the national AHSN product lead to increase awareness of commissioning processes and work collaboratively towards the successful implementation of this policy;

vii) Attend NHS England and NHS Improvement engagement events to promote your technologies, demonstrating their benefits for patients and the wider health economy;

viii) Ensure providers can purchase your product via NHS Supply Chain;

ix) Plan to onboard providers that have not yet implemented your innovation throughout 2021/22;

x) With future trajectory and uptake in mind, and in the interest of sustainability, consider your resource and capacity and ensure they are scaled appropriately for your product.

Academic health science networks

86. AHSNs are the delivery partner of NHS England and NHS Improvement Innovation, Research and Life Sciences and the AAC programmes. They are ideally placed to help both the product suppliers and NHS providers to engage with CCGs and understand the benefits of implementing these technologies.

87. The steps that AHSNs can take to help providers and suppliers' transition from the ITP programme to the MedTech Funding Mandate policy may include:

i) National AHSN product lead and local AHSNs work with the suppliers to identify eligible provider sites and the stage of adoption;

ii) Co-ordinate regional AHSNs to complete the MedTech Funding Mandate tracker provided by NHS England and NHS Improvement;

iii) Support suppliers and clinicians in their conversations with finance and operational managers to help planning and commissioning;

iv) Attend the NHS England and NHS Improvement action learning sets with providers to increase awareness of commissioning processes and work collaboratively towards the successful implementation of this policy;

v) Support NHS England and NHS Improvement in any engagement to raise awareness of the AHSNs and the MedTech funding Mandate technologies and their benefits to patients and the wider health economy;

vi) Plan with suppliers to onboard providers that have not yet implemented the innovation throughout 2021/22;

vii) Track barriers to uptake to aid compliance conversations;

viii) Report barriers to implementation and escalate provider sites experiencing challenges complying with the policy to NHS England and NHS Improvement.

Clinical standards

Use and benefits of the technologies

88. The technologies supported by the mandate in 2021/22 and their benefits are detailed in Annex 1.

89. Where providers have already implemented the innovations, it is important to capture the patient benefits and identify how these innovations are improving care pathways. The AHSNs can support this activity and provide guidance on implementation.

90. NICE guidance contains detailed product information – see Annex 1.

Clinical standards

91. Specific clinical standards should be adhered to for the correct implementation of the technologies as part of a care pathway.

HeartFlow FFRCT

92. This technology is for use in adult patients with stable, recent-onset chest pain who are offered a coronary CT angiography (CCTA) as part of the NICE pathway on chest pain (CG95) and the NICE MTG for HeartFlow FFRCT (MTG32).

93. Requirements for HeartFlow FFRCT are consistent with the Society of Coronary Computed Tomography (SCCT) guidelines for the performance and acquisition of coronary computed tomographic angiography (CCTA)[22] and standards set by the Royal College of Radiology for practice of CCTA in adult patients.[23] Organisations implementing HeartFlow must:

    i) have a 64 or greater slice CT scanner with cardiac gating capability;

    ii) have a dual syringe injector for two-phase injection;

    iii) have access to scheduled time on the scanner for CCTA;

[22] https://cdn.ymaws.com/scct.org/resource/resmgr/SCCT_guidelines_for_the_perf.pdf
[23] https://www.rcr.ac.uk/publication/standards-practice-computed-tomography-coronary-angiography-ctca-adult-patients

iv) have experience, willingness and staffing to use glyceryl trinitrate and beta-blockers (oral or IV) for proper vessel visualisation and heart rate control, respectively;

v) have an accredited CCTA reader (or equivalent experience of >150 cardiac CTs) – may be SCCT level 1+ or accredited through other organisations/fellowships;

vi) have at least one radiographer trained in CCTA and experienced in cardiac reconstructions;

vii) have the ability to meet minimum quality requirements for the HeartFlow process (minimum 8 to 10 consecutive cases pass initial quality acceptance);

viii) have an annual CCTA volume of >300 scans or previous experience with HeartFlow FFRCT;

ix) undergo a HeartFlow on-site review of its CCTA programme, training for imagers on HeartFlow requirements, review of CCTA best practices and SCCT guidelines for performance of CCTA;

x) collaborate with HeartFlow, including IT review and implementation within 30 days of a meeting with the relevant HeartFlow director.

SecurAcath

94. The MedTech Funding Mandate applies to the use of SecurAcath in patients who have a peripherally inserted central catheter (PICC) with an anticipated medium to long-term dwell time (15 days or more) with a, not those with a centrally inserted central venous catheter.

95. In line with NICE MTG34, providers adopting this technology must:

i) follow the supplier's recommended training plan and available online resources so that all frontline staff are properly trained to correctly insert, maintain and remove SecurAcath, as recommended by NICE;

ii) not use SecurAcath for anyone with a clinically documented nickel allergy;

iii) be aware that patients may be experience pain on removal of the device and local anaesthetic may be needed, particularly until staff are fully familiar with the technique;

iv) be aware that infection rates may increase if the device and catheter are not maintained and dressed according to protocol;

v) be aware that if a surgical 'nick' in the skin is used to aid catheter insertion, the risk of bleeding post-insertion related to this ‘nick’ can be managed with pressure until haemostasis is achieved, or a haemostatic patch and dressing used;

vi) be aware that initial adverse events may occur, such as skin indentation and anchor migration, until staff becomes familiar with the correct insertion and care techniques.

gammaCore

Providers adopting this technology must ensure:

i) gammaCore™ is prescribed by a headache specialist (in primary or secondary care) to all suitable patients as defined by NICE MTG46, and adhere to relevant clinical guidelines;

ii) staff are trained in the correct use and prescribing of gammaCore™.

Placental growth factor testing

Providers adopting this technology must:

i) integrate placental growth factor (PlGF)-based testing into the local pre-eclampsia pathway;

ii) offer PlGF-based testing to all suitable pregnant women, as defined by NICE DG23 and adhere to relevant clinical guidelines;

iii) engage all appropriate clinical staff in training; pathway and test interpretation;

iv) ensure that staff who perform PlGF-based tests have been trained and accredited;

v) have access to an appropriate platform on which to process the test;

vi) ensure that staff perform the test in line with the recommendations provided by the supplier;

vii) use PlGF tests in accordance with the system information package inserts. Contact Quidel for a copy of its package insert – Ref 98800EU, or

Roche Diagnostics for a copy of its package inserts – Ref 05144671 190 and 05109523 190;

viii) not report assay results if the laboratory has not met expected laboratory standards.

Annex 1: Innovations supported by the MedTech Funding Mandate from 1 April 2021

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, therefore avoiding invasive investigation and treatment.	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.heartflow.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. Further clinical benefits include no interruptions or delays from the catheter becoming dislodged. Fewer repeat procedures are needed because SecurAcath improves vessel preservation and reduces need for re-insertions. There are also fewer complications such as dislodgements, migration, thrombosis and infection.	• 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. • Reduced need for unplanned catheter removal and re-insertion.	• https://www.nice.org.uk/guidance/mtg34 • https://securacath.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
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 improve quality of life for people living with this condition.	• 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.gammacore.co.uk/
DG23 PlGF	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.	Using PlGF-based tests in addition to standard clinical assessment could result in a faster and more accurate diagnosis of pre-eclampsia, and better risk assessment for adverse outcomes in women with suspected pre-eclampsia. It could also allow women 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.	• Reduced length of stay if patient already admitted. • Admission avoidance if test carried out without admitting patient. • Reduced need for further third trimester scans. • Increased assurance reduces stress for patients.	• https://www.nice.org.uk/guidance/dg23 • https://diagnostics.roche.com/global/en/products/params/elecsys-sflt-1-plgf-preeclampsia.html • https://www.quidel.com/immunoassays/triage-test-kits/triage-plgf-test

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	72,139,797	63,011,446	9,128,351
SecurAcath	https://www.nice.org.uk/guidance/mtg34/resources/resource-impact-template-excel-4481647021	7,041,642	2,799,535	4,242,107
gammaCore	https://www.nice.org.uk/guidance/mtg46/resources/resource-impact-template-excel-7078045645	218,651,068	214,089,845	4,561,223
PlGF	https://www.nice.org.uk/guidance/dg23/resources/resource-impact-template-excel-2484575821	25,192,992	17,926,527	7,266,465
Total		**323,025,499**	**297,827,353**	**25,198,146**

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