NHS England Innovation and Technology Payment Technical Notes

2019-2020 ITP
2018-2019 ITP
2017-2018 ITT

NHS England Innovation and Technology Payment 2019 to 2020 Technical Notes

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Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England'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; and
- 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.

Contents

1. Purpose

This guidance is a supporting document to Section 3.4 of the 2019/20 National Tariff Payment System which sets out the national approach to supporting the adoption of innovation using the Innovation and Technology Payment.

This technical guidance contains the innovations, specifications, reimbursement and reporting requirements for the 2019/20 Innovation and Technology Payment, and for the innovations from 2018/19 and the 2017/19 Innovation and Technology Tariff, whose funding is continuing.

2. Background

In April 2017, NHS England launched the Innovation and Technology Tariff (ITT), an initiative designed to reduce the financial and procurement barriers experienced by commissioners and providers wanting to adopt innovative technologies in the NHS.

NHS England identified six themes where innovative technologies could make a difference in the two years from April 2017- March 2019. The ITT has been well received by industry and the NHS with over 100 sites implementing the ITT innovations. NHS England committed to build on this approach with the introduction of the Innovation and Technology Payment (ITP). In 2018 /19 the ITP tested four innovative products and technologies at national scale under a pilot approach[1].

3. The 2019/20 Innovation and Technology Payment (ITP)

The 2019/20 ITP was launched as an open competition in September 2018. Its focus was to attract entries for proven, cost effective, market ready innovations demonstrating potential to deliver significant patient outcomes and savings to the NHS. The competition culminated in a shortlist of innovations which were considered by a panel including clinicians, commissioners, providers, and representatives from NICE, AHSNs and patients. Further due diligence and commercial discussions further refined this shortlist, to identify the innovations with the most realisable benefit.

The innovations selected for the 2019/20 ITP have been through a rigorous process to check they meet the clinical and service standards required to deliver high quality clinical care. NHS England may choose to test the market for other products in the future, assuming that the positive outcomes anticipated from the 2019/20 ITP are realised. These notes set out how commissioners and providers can access the products available via the ITP.

4. Innovation and Technology Payment Innovations

This section sets out the innovations which are funded through the ITP for the 2019/20 financial year, which includes the 2018/19 ITP and 2017/19 ITT products.

NHS England is supporting four new innovation themes through the 2019/20 ITP to spread at pace across the healthcare system. These are:

1. Non-invasive vagus nerve stimulation for the treatment of cluster headaches.
2. Diagnostic placental growth factor-based test for the rule-out of preeclampsia in pregnant women.
3. High sensitivity troponin assay for the identification of myocardial infarction.

[1] The ITP uses a Direct Award under Public Contract Regulations 2015 regulation 14. The ITP is limited to 12 months within an 18-month timeframe in order to build evidence of benefits. If the benefits are realised, then NHS England may choose to undertake full market procurement.

4. Absorbable hydrogel spacer to reduce rectum radiation exposure during prostate radiation therapy.

NHS England is also supporting additional innovation themes through the Evidence Generation Fund (EGF), which will have more limited roll-out to evaluate their potential benefits. These themes are:

5. A digital app to support emergency mental health assessment.
6. An interoperable personal health record.

These themes increase our support for digital innovations compared to previous years and reflect the large number of applications from digital products.

4.1. Costing

Feedback from NHS commissioners and providers was positive about the zero-cost model used for the ITP therefore NHS England is continuing this approach for themes 1 – 4 outlined above between 1 April 2019 and 31 March 2020. For these innovations, providers order the innovations directly from the supplier at no cost and NHS England reimburses the supplier directly. For the EGF products, NHS England will use an outcome-based payment model. NHS England will pay a proportion of the costs for suppliers and complete the payment on condition of companies meeting agreed usage and outcome indicators.

5. Nationally agreed pricing for ITP innovations

NHS England will cover the costs of the innovations funded under the ITP as outlined in each specification. Additional costs associated with implementation are not covered by NHS England and should form the basis of local discussions.

This document identifies national prices agreed between NHS England and the manufacturers/suppliers providing the ITP innovations. It is likely that local commissioners and providers will choose to use these on the basis that they consider them to be the best available price. However, they are not precluded from engaging in additional negotiations, and commissioners and providers must still comply with the local pricing rules set out in the National Tariff.

6. Support and advice

The 15 Academic Health Science Networks (AHSNs) have been closely involved in developing the ITP and supporting the roll out of the ITT and ITP programmes. Each AHSN can offer a range of support to help commissioners and providers to implement the ITP and ITT innovations in local geographies. See http://www.ahsnnetwork.com for more information on AHSNs and Appendix A for a list of AHSN contacts.

For more enquiries regarding NHS England funded programmes that support innovation please contact the Innovation, Research and Life Sciences group at england.innovation@nhs.net.

7. Data Collection

To inform future work in promoting innovation, it is essential that NHS England can assess both the impact of the ITT and ITP in facilitating access to innovations and the impact of the innovations themselves (i.e. the extent to which the anticipated outcomes set out in the innovation specification are met through use of the innovations). For this purpose, providers are required to provide data on uptake and use. Details of the data reporting requirements are set out in each innovation specification.

8. ITP Innovation Specifications

The following section provides more information on each of the ITP innovations. It sets out the specification met by the innovations and explains the pricing and payment mechanisms applicable to each innovation.

9. Innovation Specification: gammaCore™ - Non-invasive vagus nerve stimulation (nVNS) for the treatment of Cluster Headaches

9.1. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is included in the Innovation and Technology Payment (ITP), regarding non-invasive vagus nerve (nVNS) stimulation for the treatment of cluster headaches purchased centrally by NHS England.

9.2. Expected Outcome

The expected outcomes from using gammaCore™ are a reduction in symptoms for patients with treatment refractory cluster headaches and consequently an improvement in quality of life. The device gammaCore™ allows patients to self-administer nVNS therapy. This stimulation causes the body to naturally disrupt the pain signals produced during a cluster headache attack. Significant healthcare cost-savings are expected from reduced medication usage, reduced cluster headache related admissions and a lower incidence of co-morbidities.

9.3. Payment / price detail

The ITP agreed price for gammaCore™ is £625 per 93 days of treatments (excluding VAT). gammaCore™ is available under the zero-cost model and is available to patients prescribed by a headache specialist in primary or secondary care. For new patients the first 93 days of treatment is supplied free to evaluate whether the treatment alleviates cluster headache symptoms. Dispensing of subsequent treatment by the company following this trial period is dependent on clinical satisfaction that the treatment is suitable and effective in the patient. Eligible NHS sites (see 9.6) can order gammaCore™ directly from the supplier at zero-cost. The gammaCore™ device is normally delivered to the patient's home. For general enquires contact customerserviceuk@electrocore.com or call 0800 678 5632.

9.4. Population Needs

National/local context and evidence base

There are approximately 65,000 cluster headache patients in England, with an estimated 5% unable to tolerate, or not gaining adequate pain relief, from current pharmacological interventions. The non-pharmacological device gammaCore™ is designed for use in these 'treatment-refractory' patients who suffer with an incredibly poor quality of life, whose treatment can cost the NHS thousands of pounds a year, and who may face surgical interventions in the further pursuit to improve their condition.

NICE states that gammaCore™ is only effective in chronic cluster headache when used as a preventative measure. In episodic cluster headache it is only effective when used as a treatment for acute pain. Using gammaCore™ would add costs to

standard care except in cases where it replaces current treatments. There are no published data to determine how likely this is. The extra costs may be offset if it reduces the number or dose of prescribed medicine or, avoids the need for more invasive treatment options.

9.5. Scope

Aims and objectives of the product

This innovation must aim to improve patient care and outcomes by effectively treating patients with treatment-refractory cluster headaches, and to reduce waste and improve efficiency by delivering more effective cluster headache management.

This innovation must:

- Be a device which allows non-invasive vagus nerve stimulation for the treatment of cluster headaches.
- Be supported by an appropriate clinical evidence-base and be compliant with the procedure described in NICE Guidance IPG552.
- Be a CE marked device

Population covered

This innovation must be appropriate for use in:

- Patients who suffer from cluster headaches who have not responded to typical therapy offered by the NHS.

9.6. Clinical Standards

Sites adopting this technology must:

- Ensure gammaCore™ is prescribed by a headache specialist (in primary or secondary care)
- Ensure staff are trained in the correct use and prescribing of gammaCore™. electroCore provides training at no extra cost, and participation is highly recommended. Support is also available via the gammaCore™ website. To access these training programs please contact Paul.edey@electrocore.com.

NOTE: Any Qualified provider (AQP) sites are eligible for this programme, if prescribing to NHS patients. Non-NHS patients are not eligible for inclusion.

Exclusion criteria

- Non-NHS patients
- Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
- Patients diagnosed with narrowing of the arteries (carotid atherosclerosis)
- Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
- Paediatric patients
- Pregnant women

- Patients with clinically significant hypertension, hypotension, bradycardia, or tachycardia
- Patients with a metallic device such as a stent, bone plate, or bone screw implanted at or near their neck
- Patients using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone)

NOTE: This list is not all inclusive. Please refer to the gammaCore™ Instructions for Use for all the important warnings and precautions before using or prescribing this product.

Applicable NICE reviews

- gammaCore™ for cluster headache: see MedTech Innovation Briefing 162

9.7. Reporting

At the end of each quarter, providers must report back on the following minimum data set:

Report for previous financial year:

- Number of patients using gammaCore™. This is only required for the first report.

Report for each quarter of the current financial year:

- Number of patients who have used gammaCore™ during this period of reporting.
- Number of patients who have tried gammaCore™ but discontinued treatment.
- Anonymised clinical outcomes (cluster headache severity and frequency) of each patient using gammaCore™
- Quality of life score of each patient using gammaCore™

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data, please contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings:

Year_Quarter_Site name_ gammaCore™ _Submission date

10. Innovation Specification: Elecsys® immunoassay sFlt-1/PlGF test and Triage PlGF – Placental growth factor-based tests for ruling out pre-eclampsia for at least 7 days

10.1. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is covered under the Innovation and Technology Payment (ITP), regarding a placental growth factor (PlGF) based test for the identification or rule-out of pre-eclampsia purchased centrally by NHS England.

10.2. Expected Outcome

The expected outcomes from using a PlGF-based test for the identification or rule out of pre-eclampsia include better risk assessment for adverse outcomes, better resource targeting of out-patient clinic visits, ultrasound scans, cardiotocography (CTG) and hospital admissions, and lower utilisation of neonatal bed nights and intensive care bed nights.

For those women in whom pre-eclampsia has been ruled out, they may be managed as an out-patient for an alternative diagnosis, may require fewer clinic visits, and, if appropriate, can safely return to community care. Providers can make savings through a reduction in bed days and may also increase productivity through better resource targeting and increased available clinical staff time.

10.3. Payment / price detail

Two suppliers are being supported under the ITP programme 2019/20. NHS England may support additional suppliers within the programme timeframe.

NHS Trusts can order either test directly from the supplier under the zero-cost model.

Supplier	Test	Cost	Contact
Quidel Ireland Limited	Triage PlGF test	£70 per test which equates to £84 reportable	Quidel Customer Services: +44 (800) 3688248 (Option 1 for Customer Service), Web form: https://www.quidel.com/support/customer-support, or by e-mail to: emeacustomerservice@quidel.com
Roche Diagnostics	Elecsys® immunoassay sFlt-1/PlGF ratio test	£94 per reportable	burgesshill.accessinnovation@roche.com

10.4. Population Needs

National/local context and evidence base

NICE states that either the Triage PlGF test and the Elecsys® immunoassay sFlt-1/PlGF ratio, when used with standard clinical assessment and subsequent clinical follow-up, are recommended to help rule-out pre-eclampsia in women presenting with suspected pre-eclampsia between 20 weeks and 34 weeks plus 6 days of gestation. NICE states that both tests are cost saving compared with standard clinical assessment.

10.5. Scope

Aims and objectives of the innovation
This innovation must aim:

- To help rule-out pre-eclampsia through better risk assessment for adverse outcomes
- To improve resource targeting (out-patient clinic visits, ultrasound scans, CTG, and hospital admission)
- If appropriate, in women who are ruled-out for pre-eclampsia, to return them to community care.
- To deliver savings and make more effective use of NHS resources by avoiding inappropriate hospitalisation.

Innovation description
This innovation must:

- Be a CE-marked PlGF-based diagnostic test to allow the rule-out of pre-eclampsia in pregnant women.
- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in DG23.

Population covered
This innovation must be appropriate for use in:

- Pregnant women suspected of pre-eclampsia

10.6. Clinical Standards

Acceptance Criteria

NHS Sites adopting this technology must:

- Integrate PlGF-based testing into the local pre-eclampsia pathway
- Offer PlGF-based testing to all suitable pregnant women, as defined by DG23
- Engage all appropriate clinical staff in training; pathway and test interpretation
- Ensure that staff who perform PlGF-based tests have been trained and accredited

- Have access to an appropriate platform on which to process the test
- Adhere to relevant Clinical Guidelines and in line with the Trusts' internally agreed clinical pathways
- Ensure that staff perform the test in line with the recommendations provided by the supplier:
- PlGF tests should be used in accordance with the system information package inserts. Contact Quidel for a copy of their package insert – Ref 98800EU or Roche Diagnostics for a copy of their package inserts - Ref 05144671 190 and 05109523 190.
- Assay results should not be reported if laboratory standards have not been met or failed to meet expected laboratory standards.

NOTE: Sites without access to the required platform who wish to adopt PlGF testing would be required to enter into a contract negotiated directly with the supplier. The ITP programme funding does not cover the costs associated with this.

Exclusion Criteria

- PlGF-based testing should not be used for asymptomatic screening or for women in whom there is not a reasonable suspicion of pre-eclampsia

Applicable NICE reviews

- PlGF-based testing to help diagnose suspected pre-eclampsia, see NICE DG23

10.7. Reporting

At the end of each quarter, providers must report back the following minimum data set:

Report for previous financial year:

- Number of PlGF tests in the previous 12 months. This is only required for the first report.

Report for each quarter of the current financial year:

- Report for each quarter of the current financial year: the number of PlGF-based tests used
- Number of women sent home with a test result which indicates no pre-eclampsia at least 7 days
- Number of pregnant women who were candidates for a PIGF-based test; i.e., who present to health services with possible pre-eclampsia before 34 weeks plus 6 days gestation
- Number of pregnant women in this target group who had hypertension
- Number of pregnant women in this target group who received a PIGF-based test

- Number of pregnant women who needed hospital admission within the rule-out period

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data, please contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings:

Year_Quarter_Site name_PlGF_Submission date

11. Innovation Specification: Elecsys Troponin T-Hs (TnT-hs) to run a High Sensitivity Troponin Assay with a rapid rule-out algorithm for the identification of myocardial infarction

11.1. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is included in the Innovation and Technology Payment (ITP), with respect to the use of the high-sensitivity troponin assay as purchased centrally by NHS England.

11.2. Expected Outcome

The expected outcomes from using the Troponin T high-sensitive assay supplied by Roche Diagnostics as part of a rapid algorithm and in conjunction with clinical decision making is reducing unnecessary time-to-discharge. The choice of rapid algorithm used includes the 0h/1h protocol, the 0h/3h protocol, or any other protocol which is under three hours. Patients who receive a rapid rule out of a Non-ST-elevation myocardial infarction (NSTEMI) can be directed to more appropriate treatment. Providers can make savings from a reduction in the length of stay of people presenting at an emergency department with chest pain, and providers can more often achieve the best practice tariff for same day emergency care.

11.3. Payment / price detail

One supplier is currently supported under the ITP programme 2019/20. NHS England may support additional suppliers within the programme timeframe.

The ITP agreed price for Elecsys® Troponin T high-sensitive assay product is £11.24 per reportable (defined as the actual costs for running the two assays per reported result excluding staff, accommodation and equipment costs e.g. only consumables and materials for quality control etc). NHS Trusts can order directly from Roche Diagnostics under the zero cost model. However they will only be compensated if they can demonstrate that they are achieving the rapid rule out pathway change. Contact burgesshill.accessinnovation@roche.com.

11.4. Population Needs

National/local context and evidence base

Chest pain, with the suspicion of myocardial infarction (MI), is responsible for around 700,000 Emergency Department attendances per year and over 253,765 emergency admissions in England and Wales [1]. This accounts for approximately 5% of all emergency admissions. However, there are many other possible causes of chest pain, therefore it is important to diagnose true MI cases as early as possible to ensure access to effective treatment, as well as rule-out non-MI cases to route to more appropriate treatment and avoid unnecessary hospital admission. NICE DG15 states that using high-sensitivity assays with rapid algorithms enables earlier detection of changes in troponin levels. This allows NSTEMI to be ruled out within 4

hours, if the test results are available within 3 hours of presentation to the emergency department.

11.5. Scope

Aims and objectives of the innovation
This innovation must aim to:

- Increase the number of emergency department patients who receive a rapid rule out of non-ST segment elevation myocardial infarction (NSTEMI)

Innovation description

This innovation must:

- Be a high sensitive assay to detect lower levels of troponin in the blood than standard assays, used with a rapid algorithm leading to improved, earlier detection of acute MI
- Have a class II CE Mark
- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in NICE DG15.

Population covered

This innovation must be appropriate for use in:

- People presenting to an emergency department with chest pain and suspected acute coronary syndrome for the early rule out of non-ST-segment elevation myocardial infarction (NSTEMI).

11.6. Clinical Standards

Acceptance Criteria

NHS sites adopting this technology must:

- Implement a new pathway for the use of Troponin Assay with a 1/3 hour rapid rule out algorithm
- Have access to a platform on which to run Elecsys® Troponin T high-sensitive assay within the rapid-rule out pathway. This may exclude sites which outsource their laboratory service
- Deliver all non-laboratory operator related training. This would include but is not limited to clinical training to NHS stakeholders affected by clinical pathway changes
- Elecsys® Troponin T high-sensitive assay should be used in accordance with the system information package insert, relevant Clinical Guidelines and in line with their internally agreed clinical pathways. Please contact Roche Diagnostics for a copy of their package insert - Ref 05092744 190

NOTE: Sites without access to the required platform who wish to adopt the Troponin T high sensitive assay would be required to enter into a contract negotiated directly

with the supplier. The ITP programme funding does not cover the costs associated with this.

Exclusion Criteria

- Troponin T high-sensitive assay should only be used in accordance with the package insert that lists any potential exclusion criteria and should not be used out with the package insert recommendations. For example, report a result on a sample with a known interference above specified threshold.
- Troponin T high-sensitive assay results should not be reported if laboratory standards have not been met or failed to meet expected laboratory standards. For example, but not limited to, a failed analyser quality control.

Applicable NICE reviews

Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in NICE DG15

11.7. Reporting

At the end of each quarter, providers must report back on the following minimum data set:

Report for previous financial year:

- Number of patients who have received a high-sensitive troponin assay within a 1-3 hour pathway in the reporting period
- Number of patients who have received a high-sensitive troponin assay above a 3 hours pathway in the reporting period.

Report for each quarter of the current financial year:

- Number of patients who have received high-sensitive troponin assay within a 1-3 hour pathway in the reporting period
- Number of patients who have received a high-sensitive troponin assay above 3 hours in the reporting period
- Number of patients admitted for follow up treatment after the use of a high-sensitive troponin assay
- Number of patients who were discharged following the use of a high-sensitive troponin assay

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data, please contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings:

Year_Quarter_Site name_Troponin_Submission date

12. Innovation Specification: SpaceOAR™ Hydrogel – Absorbable hydrogel spacer to reduce rectum radiation exposure during prostrate radiotherapy

12.1. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific detail as to the basis on which this product is included in the Innovation and Technology Payment (ITP) with respect to the reduction of rectal radiation exposure during prostrate radiotherapy purchased centrally by NHS England.

12.2. Expected Outcome

The expected outcome from using SpaceOAR™ hydrogel is a reduction in rectal radiation and therefore damage during radiotherapy for prostate cancer. This is associated with a reduction in long-term rectal complications and improved quality of life following radiotherapy for prostate cancer [1]. SpaceOAR™ hydrogel is also clinically proven to minimise urinary and sexual side-effects of radiation therapy. Use of the product should also help to reduce waste and improve efficiency by delivering more effective surgical interventions. This product may be conducive for the implementation of hypofractionation radiotherapy, which would free up hospital resources.

12.3. Payment / price detail

The ITP agreed price for SpaceOAR™ is £2000 (excluding VAT) per unit. SpaceOAR™ is available under the zero-cost model. Providers can order the product directly from Boston Scientific at zero-cost. Contact: unitedkingdomsalessupport@bsci.com

Phone: +44 344 8004512

The part number is SO-1010 and orders must be clearly marked ‘ITP – zero cost model’. To order the product, hospitals must send an e-mail to the above address with reference to the ITP programme, SpaceOAR™ purchase order number, number of units required, delivery address and zero value. Specific details on this process will be provided by Boston Scientific and the local AHSN.

Please note that participation in the scheme is limited and to be agreed with Boston Scientific prior to placing any orders. All participating SpaceOAR™ sites must agree to enter into Boston Scientific’s Intent to Train programme.

[1] Hamstra DA, et al. Continued benefit to rectal separation for prostate radiation therapy: Final results of a phase III trial. Int J Radiat Oncol Biol Phys. 2017 Apr 1;97(5):976-85.

There is a minimum order quantity of four units per order, and the product can only be ordered in multiples of four. More information about SpaceOAR™ hydrogel is available at Boston Scientifics's website.

12.4. Population Needs

National/local context and evidence base

Radiotherapy is a proven effective treatment for prostate cancer and is continually advancing. The success of radiotherapy in the treatment of prostate cancer is dependent on several factors including the radiation dose to the tumour and the avoidance of radiation to nearby healthy structures (organs-at-risk), particularly the rectum. While higher doses of radiation have been shown to improve survival outcomes, they are also associated with increased risk of rectal toxicity and other urinary and sexual complications that can significantly reduce a patient's long-term quality of life.

12.5. Scope

Aims and objectives of the innovation
This innovation must aim to:

- Improve patient outcomes and care by reducing rectal toxicity following prostrate radiotherapy for prostate cancer in adults.

Innovation description

This innovation must:

- Be an absorbable hydrogel spacer to temporarily position the rectum away from the prostate during radiotherapy (about three months), to minimize urinary, sexual and bowel side effects for prostate cancer patients undergoing radiation therapy.
- Have a class III CE Mark approved by a registered notified body.
- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in IPG590

Population covered

This innovation must be appropriate for use in:

- Those undergoing prostrate radiotherapy for the treatment of prostate cancer, who meet the acceptance and exclusion criteria outlined below. It is expected that decisions on use with individual patients are based on the quality criteria outlined in 12.6.

12.6. Clinical Standards

Acceptance Criteria

Indication: SpaceOAR™ System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy (about three months) for prostate cancer and in creating this space it is the intent of SpaceOAR™ System to reduce the radiation dose delivered to the anterior rectum.

NHS Sites adopting this technology must:

- Only use SpaceOAR™ hydrogel using compatible equipment, under ultrasound guidance using a transrectal ultrasonography (TRUS) side-fire ultrasound probe and stepper ultrasound stabilisation system
- Ensure staff are trained in the correct use of SpaceOAR™ Hydrogel, following the supplier's recommended training plan and making use of available online resources. Boston Scientific provides a range of training platforms at no extra cost to allow certified appliers to begin offering SpaceOAR™ hydrogel to patients
- Ensure all SpaceOAR™ appliers sign up to the Boston Scientific Intent to Train Programme
- Ensure Procurement follow the guidance for ordering the product as detailed in 12.3.
- Adhere to the Instructions for Use

Applicable NICE reviews

- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in IPG590.

12.7. Reporting

At the end of each quarter, providers must report back on the following minimum data set:

Report for previous financial year:

- Number of patients using SpaceOAR™. This is only required for the first report

Report for each quarter of the current financial year:

- Number of patients who have used SpaceOAR™ during this period of reporting

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data, please contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings:

Year_Quarter_Site name_ SpaceOAR™ _Submission date

13. Innovation Specification: Episcissors-60 – Guided mediolateral episiotomy scissors

13.1. Purpose

This specification gives NHS providers and commissioners information on Episcissors-60, a product included in the Innovation and Technology Payment programme for use in guided mediolateral episiotomy.

13.2. Expected Outcome

Approximately 15% of births in England require an episiotomy, of which around 25% of women may sustain an Obstetric Anal Sphincter Injuries (OASIS). OASIS repair, litigation and elective caesarean sections cost the NHS £57 million annually. The angle of the cut is important and NICE Guidance recommends that cuts need to be between 45 and 60 degrees to reduce the incidence of poor patient outcomes, reconstructive surgery and litigation costs. The use of angled scissors in episiotomies therefore should improve patient experience and outcomes and reduce OASIS repair and litigation. Published evidence shows using angled scissors can lead to a reduction in OASIS between 18-50%.

13.3. Payment / price detail

The ITP programme uses a reimbursement model for Episcissors-60.

For existing sites (who submitted data in/prior to Q4 2018) NHS England will continue to reimburse NHS providers £16 per use, up to a maximum of 40 uses per Episcissor-60 (i.e. £16 x 40). The payment will be reimbursed by NHS England on a quarterly basis based on submission of a minimum data set (MDS). See section 5 in the specification below for reporting instructions.

For new sites (2019/20) NHS England will reimburse NHS providers the cost of the Episcissors-60 (£384 per Episcissor-60 including VAT) to sites who implement this innovation in the 2019/20 financial year. Payment will be reimbursed by NHS England on a quarterly basis based on submission of a minimum data set (MDS). See section 13.7 in the specification below for reporting instructions.

Product availability:

The Department of Health and Social Care have centrally procured a number of Episcissors-60. Providers can purchase the Episcissors-60 (£320 excluding VAT per scissor) via the NHS Supply chain:

13.4. Population Needs

National context and evidence base

An episiotomy is a procedure performed during labour, in which a woman's vaginal wall and perineum (the area between the vagina and anus) are cut in order to allow

the baby to pass through the vagina more easily.[3] In 2011/2012, 15.2% (101,678) of all births in England required an episiotomy.[4] Studies have demonstrated that where clinically indicated, mediolateral episiotomy can protect against obstetric anal sphincter injuries (OASIS), which are the most common cause of faecal incontinence in otherwise healthy women. They occur in 2.9% of births in the UK overall, in 6.1% of first-time births and 1.7% of births to women who have given birth two or more times before.[5] A meta-analysis found that 30% of women who had an OASIS still had symptoms one year after childbirth.[6] Symptoms can include faecal urgency, inability to control wind and uncontrolled bowel movements.[7]

Guidance from NICE and the Royal College of Obstetricians and Gynaecologists (RCOG) states that where indicated, a mediolateral approach to episiotomy is preferable. Evidence supports an angle of incision 60 degrees from the perineal midline to maximise the effectiveness of the procedure and minimise the risk of complications.[8,9]

13.5. Scope

Aims and objectives of innovation

This innovation must aim to:

- Prevent avoidable harm by removing human error; specifically, in reducing the incidence of obstetric anal sphincter injuries and of 3rd/4th degree tears

Innovation description

This innovation must:

- Be a surgical incision device
- Offer an alternative to the standard episiotomy scissors (for which the cutting angle must be estimated), to facilitate accurate mediolateral episiotomy during labour at 60 degrees to the perineal midline, as per the recommendations of NICE and the RCOG
- Be designed for use by qualified midwives and obstetricians trained in mediolateral episiotomy

[3] HESonline (2012) NHS Maternity Statistics – England, 2011–2012. Published December 06, 2012 [Online accessed 12 March 2015]]
[4] Ibid
[5] Thiagamoorthy G, Johnson A, Thakar R et al. (2014) National survey of perineal trauma and its subsequent management in the United Kingdom. International Urogynecology Journal 25: 1621–7
[6] Oberwalder M, Connor J, Wexner SD (2003) Meta-analysis to determine the incidence of obstetric anal sphincter damage. British Journal of Surgery 90: 1333–7
[7] Dudding TC, Vaizey CJ, Kamm MA (2008) Obstetric anal sphincter injury: Incidence, Risk Factors, and Management. Annals of Surgery; 247: 224–37
[8] Kalis V, Karbanova J, Horak M et al. (2008) The incision angle of mediolateral episiotomy before and after repair. International Journal of Gynaecology and Obstetrics 103: 5–8
[9] Stedenfeldt M, Pirhonen J, Blix E et al. (2012) Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study. British Journal of Obstetrics and Gynaecology 119: 724–30

Population covered

This innovation must be appropriate for use in:

- Pregnant women during labour whom an episiotomy is indicated
- Secondary care midwifery and obstetric units, primary care midwifery units or birth centres and during home births

13.6. Clinical Standards

This innovation must:

- Be CE-marked as a Class I medical device
- Be supported by a clinical evidence-base: NICE Medtech Briefing (MIB33) recommends, the EPISCISSORS-60 as the sole guided mediolateral episiotomy scissors on the market compliant with EU health and safety requirements

Applicable Service Standards

Applicable NICE reviews

Episcissors-60 for guided mediolateral episiotomy: Medtech innovation briefing - MIB33 (published July 2015)

Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

Royal College of Obstetricians and Gynaecologists: Third- and Fourth-degree Perineal Tears, Management (Green-top Guideline No. 29)

13.7. Reporting

Reimbursement for this product is generated through the reporting of clinical outcomes in a minimum data set (MDS). The MDS should be submitted on a quarterly basis within 20 working days of quarter end. MDS received after the reporting date may not be eligible for payment.

NHS providers will be given a purchase order number, based on the payment models shown in section13.3, which can be used to claim reimbursement on a quarterly basis. Payment will be made directly to the NHS provider based on the MDS submission.

For each period of activity claimed providers must report back on the following minimum data set:

- Number of mothers sustaining an obstetric anal sphincter injury following a guided mediolateral episiotomy during each quarter of the previous year. This is only required for the first claim
- Number of mothers sustaining an obstetric anal sphincter injury following a guided mediolateral episiotomy during each period of reporting

- Number of guided mediolateral episiotomies undertaken using a) the Episcissors-60 and b) any other approved device during this period of reporting
- Average discharge time of mothers who have received a guided mediolateral episiotomy using the Episcissors-60

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data, contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject heading:

Year_Quarter_Site name_Episcissors_Submission date

14. Innovation Specification: Non- Injectable Connector (NIC)

14.1. Purpose

This specification gives NHS providers and commissioners information on the Non-Injectable Connector (NIC), a product included in the Innovation and Technology Payment programme for use in arterial connecting systems to reduce bacterial contamination and prevent the accidental administration of medication into an artery.

14.2. Expected Outcome

Arterial cannulation is associated with complications including bacterial contamination, accidental intra-arterial injection and blood spillage. Needle-free connectors prevent blood spillage and through a one-way valve allow aspiration only thus preventing accidental administration of medication to the arterial line.

Arterial line placement is a common procedure in various critical care settings. Intra-arterial blood pressure (BP) measurement is more accurate than measurement of BP by non-invasive means, especially in the critically ill. Although rare, when wrong route drug administration occurs, it has the potential to cause serious damage to the vessel and surrounding tissue.

14.3. Payment / price detail

The ITP agreed price for this innovation is £2 per unit. This is available to providers under the zero-cost model. See section 14.6 in the specification below for reporting instructions.

Innovation availability:

The needle-free arterial Non-Injectable Connector (NIC) devices can be ordered direct from Amdel Medical (enquiries@amdelmedical.com) supplied to NHS providers under the zero-cost model. More information on the Non-Injectable Connector is available from: https://www.amdelmedical.com/products/

14.4. Population Needs

National/local context and evidence base

Patients in intensive care often require arterial access lines to provide blood pressure monitoring, arterial blood gas readings and to facilitate the collection of numerous and repetitive blood samples[10]. The administration of medication via this line is not advised, and almost never procedurally carried out because of the potential to cause serious damage to the vessel and surrounding tissue. However, given the environment usually surrounding a patient with an arterial line (a busy clinical environment, many ports, many different lines, and a need for rapid interventionist care), accidental injection of IV medication into arterial lines has been reported, including cases where the resulting necrosis has led to major amputations.

[10] The non-injectable arterial connector (NIC): A cost effectiveness assessment to improve arterial line safety - Dr Maryanne Mariyaselvam, Dr Mark Blunt, Dr Peter Young (The Queen Elizabeth Hospital, Kings Lynn), The Eastern Academic Health Science Network, Patient Safety Study FC171013/11

Accidental injection into the arterial line currently occurs partly because the standard arterial connectors do not prevent the ability to administer medication into the line. The misadministration of medication via the wrong route is classified as a ‘never event’.

14.5. Scope

Aims and objectives of the innovation

This innovation must:

- Improve arterial line safety for patients
- Minimise the risk of transmission of blood borne infections from patients to staff
- Make arterial line sampling a simpler process for staff
- Prevent incorrect administration of medication

Innovation description/care pathway

This innovation must:

- Be a needle-free connector for arterial cannulation using a one-way valve to allow aspiration only
- Be compatible with blood sampling ports and blood gas sampling devices
- Be compatible with other current NHS equipment linked with existing arterial line connectors; such as closed venous arterial blood management protection systems
- Prevent the misadministration of medication into the arterial line
- Prevent the ingress of bacteria into the arterial line
- Be suitable to remain on the arterial line for the duration of time the arterial line is used (according to individual hospital policy, between 3-7 days)
- Require minimal training for staff
- Not require any additional facilities or technologies to use the device

Population covered

This innovation must be appropriate for use in:

- Adult patients with arterial lines in critical care facilities, operating theatres, and emergency departments

Clinical standards /acceptance and exclusion criteria and thresholds

Exclusion Criteria:

- The NIC is not licensed for use in children

This innovation must:

- Be CE-marked as a Class IIa medical device
- Be supported by a sufficient clinical evidence-base: the NIC is the only such CE-marked device currently available, as per NICE Medtech Briefing [MIB85].

Applicable Service Standards

Needle-free arterial non-injectable connector. Medtech innovation briefing [MIB85]. Published date: October 2016

14.6. Reporting

Providers using the NIC are required to report to NHS England if an injection into an arterial line occurs: england.innovation@nhs.net

15. Innovation Specification: PneuX System

15.1. Purpose

This specification gives NHS providers and commissioners information on the PneuX endotracheal/tracheostomy tube, a product included in the Innovation and Technology Payment programme for use to prevent ventilator-associated respiratory infections when used in conjunction with the automated cuff pressure controller.

15.2. Expected Outcome

Ventilator-Associated Pneumonia (VAP) is defined as pneumonia that occurs 48-72 hours or thereafter following endotracheal intubation, characterised by the presence of a new or progressive infiltrate, signs of systemic infection (fever, altered white blood cell count), changes in sputum characteristics, and detection of a causative agent. Improved airway management in critically ill patients who are having mechanical ventilation can prevent these ventilator-associated respiratory infections in patients having ventilation for 24 hours or more. The PneuX system is designed to minimise the risk of bacteria or fluid entering the lungs (pulmonary aspiration) through the use of a cuffed ventilation tube and an electronic tracheal seal monitor.

15.3. Payment / price detail

The ITP agreed price for this innovation is £150 per tube. The PneuX device can be ordered directly from Qualitech, supplied to NHS providers under the zero-cost model: https://qualitechhealthcare.co.uk/contact-us or call 01628 854 042.

Availability:

Qualitech supply the breathing tubes under the above zero-cost model. The PneuX Tracheal Seal Monitor (TSM) required to use the PneuX tubing system is supplied by Qualitech on a loan basis to NHS providers when a minimum order of 24 tubes is placed by the Trust. Contact Qualitech directly for more information https://qualitechhealthcare.co.uk/contact-us

More information on the PneuX system is available from: https://qualitechhealthcare.co.uk/pneux-system

15.4. Population Needs

Ventilator-Associated Pneumonia (VAP) is a hospital-acquired infection, often defined as pneumonia occurring in patients at least 48 hours after ventilation via an endotracheal or tracheostomy tube. The presence of a tracheal tube can interfere with the normal protective reflexes of the upper airway, resulting in impaired clearance of micro-organisms, leading to VAP11.

[11] Hunter JD (2012) Ventilator associated pneumonia. British Medical Journal 344: e3325

VAP is considered a common infection in the intensive care unit (ICU)[12] with between 10% and 20% of patients who have mechanical ventilation for longer than 48 hours developing VAP. These patients appear to be twice as likely to die compared with similar patients without VAP[13] with prolonged mechanical ventilation considered a significant risk factor for VAP[14], which has an attributable mortality rate of around 30% and an estimated cost to the NHS of between £10,000-20,000 per patient.

15.5. Scope

Aims and objectives of the innovation

This innovation must aim to:

Prevent ventilator-associated pneumonia by minimising the risk of pulmonary aspiration and micro-aspiration in patients having ventilation for 24 hours or more.

Innovation description

This innovation must:

- Be an endotracheal/ tracheostomy tube system for airway management, consisting of an endotracheal or tracheostomy tube, tracheal seal monitor and an extension tube
- Replace standard endotracheal and tracheostomy tubes that have no subglottic drainage access, subglottic drainage access but with a high-volume low-pressure cuff, or no continuous cuff-pressure controller

Population covered

This innovation must be appropriate for use in:

- Intensive or critical care patients having mechanical ventilation
- Cases where the duration of intubation is expected to be more than 24 hours
- Patients for whom tracheal intubation is required during routine anaesthesia

15.6. Clinical Standards

This innovation must:

- Be CE-marked as a class III device (endotracheal/tracheal tube) and a class IIb device (tracheal seal monitor)

[12] Bouza E, Hortal J, Munoz P et al. (2006) Post-operative infections after major heart surgery and prevention of ventilator-associated pneumonia: a one day European prevalence study (ESGNI-008). Journal of Hospital Infection 64: 230–4

[13] Safdar N, Dezfulian C, Collard HR et al. (2005) Clinical and economic consequences of ventilator associated pneumonia: a systematic review. Critical Care Medicine 33: 2184-93

[14] Bauer TT, Ferrer R, Angrill J et al. (2000) Ventilator-associated pneumonia: incidence, risk factors, and microbiology. Seminars in Respiratory Infections 15: 272–79

15.7. Applicable Service Standards

The British Society for Antimicrobial Chemotherapy recommends that measures should be taken to prevent VAP by reducing aspiration via subglottic secretion drainage, correct positioning of the tube and sufficient cuff pressure to avoid aspiration and tracheal damage.
The Patient Safety First How to Guide for critical care (2008) provides advice on mechanical ventilation and the NHS ventilator care bundle. The NHS ventilator care bundle has 4 key components:

- elevation of the head of the bed to between 30 and 45 degrees
- daily sedative interruption and daily assessment of readiness to extubate
- peptic ulcer disease prophylaxis and venous thromboembolism prophylaxis
- appropriate humidification of inspired gas and appropriate tubing management

15.8. Reporting

For each period of activity providers must report back on the following minimum data set:

- Prevalence of Ventilator-Associated Pneumonia (VAP) during each quarter of the previous financial year. This is only required for the first report
- Prevalence of Ventilator-Associated Pneumonia (VAP) during this period of reporting
- Number of PneuX tubes or other approved VAP prevention devices used on patients ventilated for 24 hours or more

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data, please contact: england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address: agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings:

Year_Quarter_Site name_Pneux_Submission date

16. Innovation Specification: myCOPD Web-based application for the self-management of chronic obstructive pulmonary disease

16.1. Purpose

This specification gives NHS providers and commissioners information on myCOPD, a product included in the Innovation and Technology Payment programme for use in the self-management of chronic obstructive pulmonary disease.

16.2. Expected Outcome

Managing Chronic Obstructive Pulmonary Disease (COPD) costs the NHS more than £1bn each year. Treatment can be complex, with different inhalers needing to be used in different ways, with the potential for poor treatment compliance leading to poor outcomes and potentially wasted prescribing. Improving self-management for patients with COPD is a key priority for the NHS. With no cure available for COPD good symptom management is essential to stabilise the disease and prevent recurrent flare-ups or exacerbations.

These exacerbations can require intensive treatment and may be severe enough to require hospital admission. Evidence from recent studies shows that disease-specific self-management can improve health status and reduce hospital admissions in COPD patients. App-based health education programmes such as myCOPD focus care on behaviour modification and self-management of COPD to increase the knowledge and skills the patients need to treat their own illness. Patients may better manage their condition through effective inhaler use, which supports self-care and complements face to face pulmonary rehabilitation programmes.

16.3. Licences

NHS England supported the purchase of myCOPD patient software licences in 2017 and 2018 under the ITT programme. CCGs can register these licences to patients who meet the eligibility criteria set out below.

The following patient groups are eligible for licence registration:

- Patients with severe or very severe COPD on a care pathway managed by primary or secondary care
- Patients discharged from hospital as part of the COPD discharge bundle (which can be linked to the Best Practice Tariff)

16.4. Information Governance

NHS providers must meet the information governance requirements set out below for release of licences:

- Be NHS Information Governance Toolkit (IGT) compliant
- Use NHS IT servers for secure hosting of data
- If the products are NHS IGT compliant then they can be used in the NHS

Many providers will use other cloud services that provide the same level of security as being on NHS servers and pass IGT.

16.5. Training and implementation support

The training and digital transformation support to the implementation of myCOPD is available at additional cost from the mymhealth digital transformation team. Contact info@mymhealth.com or call 01202 299 583 for further information.

16.6. Reporting

For each period of activity, providers must report back on the following minimum data set:

- Number of patients receiving face to face pulmonary rehab during each quarter of the previous financial year. This is only required for the first report
- Number of patients receiving face to face pulmonary rehab during this period of reporting
- Number of patients registered on a) myCOPD and b) other approved web-based service during this period of reporting

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data, please contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings:

Year_Quarter_CCG name_MyCOPD_Submission date

17. Innovation Specification: Frozen Faecal Microbiota Transplantation (FMT)

17.1. Purpose

This specification gives NHS providers and commissioners information on Frozen Faecal Microbiota Transplantation (FMT), supplied thorough the ITP programme for use in management of patients with recurrent *Clostridium difficile* infection (CDI). This includes details of what is covered under the ITP, in terms of the characteristics of FMT to be supplied and the way in which it should be used within care pathways by the purchasing Trusts, developed with the help of The University of Birmingham Microbiome Treatment Centre.

17.2. Expected Outcome

CDI can be a serious, life threatening condition. It can occur in patients undergoing antibiotic treatment, in particular those on broad-spectrum antibiotics. Older people over 65, patients with weakened immune systems and those with bowel conditions are also at an increased risk of CDI.[15]

CDI rates are climbing in frequency and severity, and the spectrum of susceptible patients is expanding beyond the traditional scope of hospitalized patients receiving antibiotics. Faecal microbiota transplantation is increasingly accepted as an effective and safe intervention in patients with recurrent disease, with cure rates of > 90% consistently reported from multiple centres.

FMT is the provision of a screened specially prepared stool administered via a nasal tube into the intestine to restore the balance of bacteria in the gut. Treatment by the colonic route through a colonoscope is also a valid form of FMT administration. FMT is a NICE recommended treatment for recurrent CDI not responding to antibiotic treatment and can be considered for patients with severe CDI. FMT is a better treatment than antibiotics for recurrent CDI at a comparable cost and has been shown to reduce length of hospital stay.

17.3. Payment / price detail

The agreed price for this innovation is £650 per FMT aliquot. Transport costs are free within a 3-hour transportation area. Where the provider lies outside this transportation area from the University of Birmingham Microbiome Treatment Centre, the transport costs will be covered, up to an additional cost of £661 per aliquot. FMT can be ordered from the University of Birmingham Microbiome Treatment Centre, supplied to NHS providers under the zero-cost model.

[15] National *Clostridium difficile* Standards Group. Report to the Department of Health, February 2003. http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947372533

Availability:

Orders for FMT can be placed with the University of Birmingham Microbiome Treatment Centre (UoBMTC) via the following email address: bhs-tr.FMT@nhs.net
Tel Contact: 0121 414 4547

17.4. Population Needs

National context and evidence base

Clostridium difficile bacteria can live harmlessly in the gut of approximately 5% of healthy people. However, the decline of intestinal bacteria as people get older, together with a reduction in immune response, increases the risk of CDI in the elderly, with over 80% of cases reported occurring in people aged over 65. Prevalence can be as high as 20% among elderly patients in hospital and as high as 50% in some long-term care facilities.[16] The use of certain medications (such as proton pump inhibitors or H2 receptor antagonists) can also increase the risk of CDI, as can antibiotics or immunosuppressive agents (due to the way in which they change the balance of bacterial species in the gut). Symptoms can range from mild to severe and can at times be life-threatening. The risk of death increases in patients with multiple comorbidities.[17] [18]

Initial treatment involves rehydration and antibiotic therapy. Most people recover successfully. Relapse (defined as a second episode occurring within 2–8 weeks) occurs in about 20% of patients treated initially with either metronidazole or vancomycin and in 50-60% of patients following a second episode of CDI.[19] [20] [21] Recurrent or refractory CDI can be defined as two or more treatment failures within three months of the initial case. Typically, patients with recurrent CDI have significant co-morbidities, compromised immune systems and poor health outcomes overall. Samples donated as part of the FMT treatment are an underused, but very effective, product for tackling recurrent CDI.[22] [23]

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[16] Asymptomatic Carriers Are a Potential Source for Transmission of Epidemic and Nonepidemic Clostridium difficile Strains among Long-Term Care Facility Residents: Riggs et al, October 2007. http://cid.oxfordjournals.org/content/45/8/992.full.pdf+html

[17] National Institute for Health and Care Excellence ESNM1 Clostridium difficile infection: fidaxomicin July 2012, http://www.nice.org.uk/advice/esnm1/chapter/Relevance-to-NICE-guidance-programmes

[18] National Institute for Health and Care Excellence IPG485 Faecal microbiota transplant for recurrent Clostridium difficile infection. March 2014

[19] Kelly CP, LaMont JT. Clostridium difficile--more difficult than ever. N Engl J Med. 2008;359(18):1932-1940

[20] Johnson S. Recurrent *Clostridium difficile* infection: causality and therapeutic approaches International Journal of Antimicrobial Agents 33 (2009) S33-S36

[21] Public Health England. Updated guidance on the management and treatment of Clostridium difficile infection, May 2013

[22] Sofi AA, Silverman AL. et al. Relationship of symptom duration and faecal bacteriotherapy in Clostridium difficile infection-pooled data analysis and a systematic review. Scandinavian Journal of Gastroenterology 2013; 48(3): 266-273.

[23] van Nood E, Vrieze A. et al. Duodenal infusion of donor faeces for recurrent Clostridium difficile. New England Journal of Medicine. 2013; 368 (5): 407- 415.

17.5. Scope

Aims and objectives of the innovation

FMT donor samples aim to offer an additional effective option for reducing the risk of repeated CDI relapse in patients with recurrent CDI and for treatment of severe CDI, by rebalancing the patient's bowel flora. Use of the donor samples will reduce morbidity and mortality for patients with recurrent CDI. Donor samples will reduce the risk of avoidable harm and provide a positive experience and enhanced quality of life for patients.

Service description/care pathway

Where FMT is being considered as appropriate for an individual with CDI the clinical team looking after the patient should contact UoBMTC using the secure email address given above. The process is described in full below:

- The clinical team will contact UoBMTC to express their interest in using FMT to treat their patient. The initial point of contact being via email
- UoBMTC will supply the clinical team with a copy of their FMT request form, order form, clinical protocol, terms and conditions of supply and a patient information leaflet
- Upon receipt of both the completed FMT request and order form (sent to the secure inbox), the UoBMTC clinical team will access the request for its clinical suitability
- If the patient is deemed eligible for FMT the UoBMTC will contact the blood bike service to arrange delivery of FMT to the requesting site: provision will be on a named patient basis in accordance with the conditions of the MHRA Specials licence
- UoBMTC will contact the requesting team to confirm their request has been ratified and the time of expected delivery of their FMT. Informed consent should be obtained from the patient in accordance with local practise prior to the administration of FMT
- If FMT cannot be delivered by Blood Bikes, an alternative courier is to be organised by the requesting Trust to an agreed delivery point. For sites that are at great distance, UoBMTC may arrange FMT to be delivered by a temperature monitored courier service, and the FMT will be supplied frozen
- FMT must be used within the time frame outlined on the UoBMTC validation certificate which is supplied alongside the FMT aliquot(s). This validation certificate is to be retained in the patients' clinical notes
- The route of delivery and protocol associated with this will be as per local practice

FMT procedures will be recorded using the following coding:

- ICD-10 A04.7 Clostridium difficile enterocolitis (if applicable) or Not a case of Clostridium difficile enterocolitis
- G48.8 Other specified operations on stomach
- Y37.8 Other specified introduction of other substance into organ
- FZ25A Therapeutic Endoscopic or Intermediate Stomach or Duodenum Procedures 19 years and over OR
  FZ25B Therapeutic Endoscopic or Intermediate Stomach or Duodenum Procedures 19 years and under

Population covered:

Patients who have had recurrent CDI which has not been successfully treated with standard antibiotic treatment and who meet the acceptance criteria

Any acceptance and exclusion criteria and thresholds

Acceptance Criteria:

- Confirmed recurrent or refractory CDI, defined as two or more treatment failures following appropriate antibiotic treatment and microbiologically proven active infection
- Aged over 16 years
- Appropriate swallow reflex to reduce the risk of aspiration post-procedure.

Exclusion Criteria:

Possible contra-indications are shown below. None are absolute contra-indications by themselves and all cases should be discussed:

- Aged under 16 years
- Significant swallowing difficulty
- Ulceration/bleeding of the upper gastrointestinal tract
- Severe peptic or duodenal ulcerative disease
- Neutropenia
- Long-term immunosuppression via steroids or other immunomodulators
- Current inflammatory bowel disease, colitis, perforated bowel or increased
- Permeability of the bowel likely to lead to translocation of bacteria
- All patients will be assessed and considered on a case-by-case basis
- Life threatening food allergy e.g. peanuts

Patients who have had two previous FMTs from different donors will always need to be assessed for eligibility.

Other considerations:

Food allergies must be recorded but this will not preclude donation from screened donors as per the joint Hospital Infection Society/British Society of Gastroenterology guidelines commissioned by the UK Microbiome For Health Expert Panel.

Risks:

- Perforation of (making a hole in) the alimentary canal during naso-jejunal tube placement (<1 in 10,000)
- Risks associated with colonoscopy (perforation/haemorrhage <1 in 1000)
- Infection – actual risk uncharacterised, but less than 1 in 100. Including possible peritonitis, enteritis, aspiration pneumonia
- Transfer of microbiologically uncharacterised material
- Bleeding – reported in one case to date, and not clearly linked to FMT (1 in 350)
- Diarrhoea is common immediately following the procedure but resolves over the next 5-7 days (>1 in 10)
- Constipation (1 in 350)
- Irritable bowel like syndrome has been reported in 5 of 350 cases
- Failure to cure (19% after first FMT, 6% after two FMTs)

Benefits:

- Overall cure rate of 94% (81% after first FMT) in recurrent CDI compared with 31% with standard therapy
- Low recurrence rate of 6%, compared with 69% on standard therapy in recurrent CDI

Service Standards

FMT will be used as described in the Terms and Conditions associated with the provision of this service and in accordance with existing European Guidelines and British Guidelines which have been submitted for publication.[24]

Donor stools will be sourced from the UoBMTC stool bank and derived from donors screened for general health in accordance with current protocols and international guidelines. Donors will be healthy adults (aged between 18 and 50), with a BMI not greater than 25 or below 18.5, non-smokers, with no family history of gastrointestinal disorders and no indication of / risk factors for an infection. At the time of donation, donors will be screened for blood borne and faecal pathogens as per the UoBMTC protocol and in accordance with European and British guidelines.

[24] Cammarota G, Ianiro G, Tilg H, et al. Gut 2017; 66:569-580

Once delivered FMT will be administered locally according to local FMT protocols. The UoBMTC protocol will be available for guidance if requested.

UoBMTC will keep a registry of donors and patients treated with outcome data to inform future practice and to provide a “look back” facility for adverse event reporting as per the conditions of the MHRA Specials licence.

Patient experience

Hospitals are expected to provide the following standards of patient experience;

- All patients are to be treated with dignity & respect
- Care is delivered in a clean and pleasant environment that is safe and hygienic for patients, carers/relatives and staff
- Processes should be in place to ensure that all patients are able to communicate with relevant staff and understand their diagnosis & treatment. This includes access to translation services and support for people with particular needs e.g. deaf patients and patients with learning disabilities (as appropriate).
- Patients attending the service may be accompanied by carers and relatives and provision should be made to accommodate them whilst waiting.

17.6. Interdependence with other services/providers

The UoBMTC operates under an MHRA Specials licence which is a variation of an existing licence relating to the manufacture of stem cells. The latter is held by the Advanced Therapies Facility (ATF) at the University of Birmingham and UoBMTC operates under the management of the ATF. Donors are processed at the Wellcome Clinical Research Facility which is an NHS facility located adjacent to UoBMTC and belonging to the Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust. The production team at UoBMTC hold honorary contracts at QEHB and are thereby able to access the secure NHS email system nhs.net, which provides a high level of security as required by the recent GDPR legislation. Donor samples are screened at the Public Health England Public Health Laboratory Birmingham, located at the Heartlands Hospital, University Hospitals Birmingham NHS Foundation Trust.

17.7. Applicable Service Standards

- NICE FMT for Recurrent CDI March: NICE IPG485 March 2014
- Updated Guidance on C. Difficile: Public Health England guidance on the management of CDI
- Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)
- Joint HIS/BSG guidelines on FMT (2018)

17.8. Applicable Local Standards

- UoBMTC Clinical Protocol
- UoBMTC C. difficile Information Sheet
- UoBMTC adverse event reporting protocol

These standards are available from the University of Birmingham Microbiome Treatment Centre (UoBMTC) via the following email address: bhs-tr.FMT@nhs.net

17.9. Applicable Quality Requirements

Applicable Quality Requirements

- Patients accepted for FMT will receive samples within a week of receipt of request
- All patients will receive a Patient Information Leaflet and be consented in accordance with national and local standards, including the risks and benefits of the procedure
- Patients will be asked to provide consent to allow UoBMTC to receive data regarding treatment outcomes
- UoBMTC will keep a register of donors and recipients
- Total procedure numbers, success, failure and complication rates for patients will be made available on request to the CCG or NHS England

17.10. Reporting

For each period of activity providers must report back on the following minimum data set:

- Hospital admission rates due to recurrent CDI in each quarter of the previous financial year. This is only required for the first report
- Number of patients receiving fidaxomicin therapy for the previous quarter. This is only required for the first report
- Hospital admission rates due to recurrent CDI for this period of reporting
- Number of patients receiving fidaxomicin therapy for this period of reporting
- Number of patients treated using FMT for this period of reporting

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data, please contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings: Year_Quarter_Site name_FMT_Submission date

18. Innovation Specification: Prostatic urethral lift systems - UroLift®

18.1. Purpose

This specification gives NHS providers and commissioners information on the UroLift® prostatic urethral lift systems, a product included in the Innovation and Technology Payment programme.

18.2. Expected Outcome

Benign Prostatic Hyperplasia (BPH) is a common and chronic condition where the enlarged prostate can make it difficult for a man to pass urine, leading to urinary tract infections, urinary retention, and in some cases renal failure. Existing treatments such as transurethral resection of the prostate (TURP), involve cutting away or removing existing tissue, usually require an hospital stay of 3 days on average and urinary catheterisation post-surgery. The UroLift® system is a tissue sparing procedure which can be performed as a day case and, increasingly is carried out under a local anaesthetic. This results in a reduction in inpatient admissions and in the costs associated with general anaesthesia. Patients receiving the UroLift® incur significantly fewer side effects, most notably a zero percent risk of permanent sexual dysfunction, along with a reduction of other post-operative complications. Healthcare teams may want to use UroLift® as an alternative to tissue-removing procedures such as transurethral resection of the prostate (TURP), holmium laser enucleation of the prostate (HoLEP) and other procedures which use tissue ablation.

18.3. Payment / price detail

The cost of this innovation is covered under the National Tariff and should be reported via Secondary Uses Service (SUS)charging per patient spell using HRG LB70C and LB70D. The cost to the commissioner is £2,538 and £2,107, respectively. The OPCS 4.7 code combination to identify Prostatic urethral lift systems under the previous National Tariff is M678 (Other specified other therapeutic endoscopic operations on prostate) + Y022 (Therapeutic endoscopic implantation of prosthesis into prostate) which will group to the LB70 Complex Endoscopic, Prostate or Bladder Neck Procedures (Male and Female) HRG Root. The new OPCS 4.8 code effective from 1st April 2017 identifies this procedure as M683, Endoscopic insertion of prosthesis to compress lobe of prostate. This code will also map to LB70. This will be effective once the HRG4+ 2017/18 Local Payment Grouper is published.

Providers should use the OPCS procedure code M68.3 for UroLift® (prostatic urethral lift) under the National Tariff Payment System. This generates a code for the service (HRG:LB70) which generates a claim for payment via SUS (Secondary Users Services).

Availability:

The UroLift® innovation can be purchased direct from the manufacturer Neotract. Direct enquiries to ukinfo@neotract.com. NHS England is working to include this product on the NHS Supply Chain.

18.4. Population Needs

National/local context and evidence base

The prostatic urethral lift has been shown in several prospective studies, including a double blind randomised controlled FDA trial, to provide rapid and sustained improvement in symptoms and flow in men with lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). Peer-reviewed outcomes from its pivotal study – LIFT – are now published up to 4 years, which demonstrate the durability of effect.

The UroLift® System is an example of a proven and durable, ambulatory treatment for urinary symptoms of enlarged prostate. Permanent implants pin back the prostate so that it does not block the urethra. Compared with current surgical care (requiring 3 days in hospital) UroLift® is a short (<30-min) procedure, performed under local anaesthetic or light sedation, with no overnight stay requirement. Unlike current surgical options, UroLift® does not cause tissue injury and therefore avoids the side effects (notably 0% sexual dysfunction risk) and well-documented complications associated with current surgical options – TURP and laser.

UroLift® has been reviewed by NICE under its Medical Technologies Evaluation Programme. Medical Technology Guidance (MTG26) was published in September 2015. The guidance states:

- The clinical and cost case for adopting the UroLift® system for treating symptoms of benign prostatic hyperplasia is supported by the evidence if it is used in a day surgery unit
- The UroLift® system relieves lower urinary tract symptoms while avoiding the risk to sexual function associated with transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). It also reduces the length of hospital stay and may be done in a day surgery unit
- The UroLift® system should be considered for use in men with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 45 years and older and who have a prostate of less than 100 cm3 and without an obstructing middle lobe*

*There are now standardised techniques for using UroLift in patients with an obstructing middle lobe. Instructions for using UroLift in these patients is now included in the approved Instructions for Use.

Recent guidelines from the European Association of Urology gave prostatic urethral lift a positive recommendation (with Level 1 evidence) for the treatment of patients with LUTS from BPH.

18.5. Outcomes

NHS Outcomes Framework Domains & Indicators

Patient outcomes

- Rapid and sustained improvement in symptoms and flow
- Improved safety and side effect profile compared with current surgical treatments
- Preservation of sexual function
- Significantly reduced post-operative complications

NHS outcomes

- Improved bed capacity
- Improved theatre capacity
- Improved outpatient capacity
- Reduced incidence of post-operative complications and readmissions following surgery
- Reduce burden on waiting times
- Cost savings through reduction in post-operative complications and readmissions

18.6. Scope

Aims and objectives of the innovation

The objectives of offering this innovation are:

- Improved patient experience - more rapid return to daily living compared with TURP and preservation of sexual function
- Improved safety – reduced risk of post-operative complications
- Reduce inpatient length of stay
- Improved theatre capacity
- Reduce outpatient visits

Service description/care pathway

The UroLift® system is used to perform a prostatic urethral lift, an alternative to current standard surgical interventions (such as TURP and laser). The UroLift® system uses adjustable, permanent implants to pull excess prostatic tissue away so that it does not narrow or block the urethra. In this way, the device is designed to relieve symptoms of urinary outflow obstruction without cutting or removing tissue.

The UroLift® system comprises two single-use components: a delivery device and an implant. The delivery device consists of a hand-held pistol grip to which a needle-

shaped probe is attached. Each UroLift® implant consists of a super-elastic nitinol capsular tab, a polyethylene terephthalate monofilament, and a stainless-steel urethral end-piece. The surgeon inserts the probe into the urethra until it reaches the prostatic urethra (the widest part of the urethral canal); a fine needle at the end of the probe deploys and secures an implant in a lobe of the prostate. One end of the implant is anchored in the urethra and the other is attached to the firm outer surface of the prostatic capsule, so pulling the prostatic lobe away from the urethra. This is repeated on the other lobe of the prostate. Typically, about four implants are used. The procedure is done as a true day-case (patients generally return home after a few hours) and is performed under a local anaesthetic or light sedation, taking less than 30 minutes.

Population covered

Men are selected and identified for the UroLift® procedure using the existing care pathway for BPH, although changes may be made to the pathway to better incorporate the UroLift® system, such as assessing the size of the prostate and the presence of a middle lobe by cystoscopy (or in some cases ultrasound). Selection for UroLift® usually involves a nurse specialist or a consultant urological surgeon assessing all men referred to secondary care. Patients are either selected from men attending outpatient clinics or from the waiting list for BPH surgery (that is, where symptoms are severe and conservative management has failed or is inappropriate) Those for whom surgery is an option are given information about all appropriate surgical options, including the UroLift® procedure. They are then seen by a consultant urological surgeon to discuss these options in more detail. Men who choose the UroLift® procedure are generally those who wish to preserve their sexual function or do not want TURP.

After confirmation that the UroLift® procedure is appropriate, the patient follows the same day-case pathway as all other urological day-case procedures. Patients typically return home after a few hours, typically without a catheter (following patient discharge, a nurse follows up by phone).

Any acceptance and exclusion criteria and thresholds

Acceptance Criteria:

Men are offered surgery for LUTS from BPH if symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are not appropriate. Referrals will come from GPs or urologists/specialist nurses in secondary care urology clinics.

UroLift® is indicated in men with LUTS from BPH who are aged 45 years and older and who have a prostate of less than 100 cm3 and without an obstructing middle lobe. Patients may also be selected from existing waiting lists of men waiting for BPH surgery.

Exclusion Criteria:

- Men aged <45
- Prostate >100cm3

Other considerations:

Geographical coverage for prostatic urethral lift systems should be determined locally. 120 NHS Trusts are currently offering surgery for BPH at a level of >50 procedures/year.

UroLift® is easily and rapidly deployable and requires minimal training and no capital outlay or infrastructure change. It should be easily available to patients as an alternative to TURP or laser, ideally with minimal travel requirements.

Theatre lists are normally scheduled so a number of UroLift® procedures can be done in a single session.

Service Standards

Patient experience

All patients should receive their treatment within the time-frame defined by National Waiting time guidelines. Patients are provided with an information sheet which explains their treatment, any post-operative self-care and what they should expect from the UroLift® procedure.

Patients typically return home on the same day as the procedure and are followed up by telephone. Their care then continues in primary care. Patients are only referred back into secondary care if there are complications that require specialist care. Hospitals are also expected to provide the following standards of patient experience;

- All patients are to be treated with dignity & respect
- Care is delivered in a clean and pleasant environment that is safe and hygienic for patients, carers/relatives and staff
- Processes should be in place to ensure that all patients are able to communicate with relevant staff and understand their diagnosis & treatment. This includes access to translation services and support for people with particular needs e.g. deaf patients and patients with learning disabilities (as appropriate)
- Patients attending the service may be accompanied by carers and relatives and provision should be made to accommodate them whilst waiting

18.7. Interdependence with other services/providers

UroLift® is easily and rapidly deployable. There are no required changes in staff numbers or grades. Surgeons (urologists) are required to undergo a 90-minute training programme provided by the manufacturer. There is additional training for the theatre staff that is also provided by the manufacturer.

Clinical support for cases is provided until the surgeon is proficient (approximately 10 cases and ongoing as requested) free of charge by the manufacturer.

Interdependencies include the following:

- Patients and carers
- CSU
- Day case surgery unit

18.8. Applicable Service Standards

- NICE guidance (MTG26)
- Recommendations in the final report of the Accelerated Access Review regarding offering UroLift® as an alternative to TURP or laser

19. Innovation Specification: HeartFlow FFRCT - Rapid diagnosis of patients presenting with new onset chest pain which is suspected to be Coronary Artery Disease (CAD) using advanced image analysis software

19.1. Purpose

This specification gives NHS providers and commissioners information on HeartFlow analysis, a software product included in the Innovation and Technology Payment programme, which is used to estimate fractional flow reserve from coronary CT angiography.

19.2. Expected Outcome

HeartFlow FFRCT Analysis is a novel software technology which estimates Fractional Flow Reserve (FFR) in coronary arteries, using CT coronary angiography (CCTA). FFR measured from invasive angiography has been used widely in clinical practice for many years and helps determine whether a person's coronary disease warrants revascularisation. Examples of revascularisation include the insertion of stents or surgical bypass grafting. The HeartFlow Analysis helps clinicians determine whether such an intervention is likely to improve a patient's longer-term outcomes or not. Improved resolution and gating of CT coronary angiography has allowed the extent and anatomical severity of coronary lesions to be assessed non-invasively, and 'HeartFlow Analysis' is the first technology to allow an assessment of FFR to be made during the same investigation.

The expected outcomes from this innovation are:

- Improved diagnosis of coronary artery disease (CAD)
- Better treatment decisions for patients who have suspected CAD

19.3. Payment / price detail

The agreed price for this innovation is £700 per analysis excluding VAT available to providers under the zero-cost model. It can be ordered directly from HeartFlow Inc. (https://www.heartflow.com/). Participating sites must meet the criteria set out in section 19.7. Contact info@heartflow.com for information.

19.4. Population Needs

National context and evidence base

CT coronary angiography is now recommended as the first diagnostic test in around 40,000 people presenting with new onset chest pain suggestive of stable angina (2017).[25] 'HeartFlow Analysis' technology is approved by NICE for the functional assessment of coronary lesions found on CT. This combined CT assessment of

[25] https://www.nice.org.uk/guidance/mtg32

coronary anatomy, and the functional significance of selected coronary lesions by FFRCT, provides valuable diagnostic and therapeutic information and may reduce the need for more invasive investigations. Based on NICE's Medical Technology Guidance (2017) there is an estimated potential net saving of £214 per patient for HeartFlow FFRCT compared with the current treatment pathway.[26]

19.5. Scope

Aims and objectives of product

This innovation must aim to improve the diagnosis of coronary artery disease and improve the patient experience by avoiding the need for invasive coronary angiography and revascularisation.

Innovation description

This innovation must:

- Be a coronary physiology simulation software package and service used for the qualitative and quantitative analysis of previously acquired computerised tomography (Digital Imaging and Communications in Medicine data)
- Improve patient care by avoiding the need for invasive coronary angiography and revascularisation

Population covered

This innovation must be appropriate for use in:

- Adult patients with stable, recent onset chest pain who are offered a coronary CT angiography (CCTA) as a part of the NICE pathway on chest pain

19.6. Clinical Standards

This innovation must:

- Be CE marked as a Class IIa software solution
- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in MTG32[27]

19.7. NHS Site Criteria

NHS sites implementing HeartFlow must meet the following criteria.

CT Data Format and Quality Requirements

Requirements for HeartFlow are consistent with the Society of Coronary Computed Tomography (SCCT) Performance of Cardiac CT Guidance Document

- 64 or greater slice CT scanner with cardiac gating capability
- Dual syringe injector for 2 phase injection
- Access to scheduled time on the scanner for CCTA

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[27] https://www.nice.org.uk/guidance/mtg32

- Experience, willingness, and staffing to use Glyceryl Trinitrate (GTN) and beta blockers (BB) (oral or IV) for proper vessel visualisation and heart rate control, respectively
- Accredited CCTA reader (or equivalent experience of >150 cardiac CTs) - may be SCCT Level 1+ or accredited through other organisations/fellowship
- At least 1 radiographer trained in CCTA and experienced with cardiac reconstructions
- Ability to meet minimum quality requirements for HeartFlow process (minimum 8/10 consecutive cases pass initial quality acceptance)
- HeartFlow on-site review of the institution's CCTA programme, training for imagers on HeartFlow requirements, review of CCTA best practices, and SCCT guidelines for performance of CCTA

Site-specific Criteria

Additional site-specific criteria to ensure broad evaluation of HeartFlow in England

- Imaging team with CCTA expertise meeting recommendations set by Royal College of Radiology and Society of Coronary Computed Tomography as well as a demonstrated ability to meet minimum CT quality requirements
- Annual CCTA volume of > 700 scans or prior experience with HeartFlow

If your site currently has an annual CCTA volume of >600 scans and you would like to be considered for this programme contact england.innovation@nhs.net

NHS sites are required to:

- Collaborate with HeartFlow, including IT review and implementation within 30 days of meeting with HeartFlow IT Director
- Have broad support across radiology, cardiology, and site administration with ability and commitment to enable and educate physicians to follow a CT±FFRCT pathway
- Provide health economic data to NHS England/HeartFlow

Applicable Service Standards

HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography: Medical technologies guidance [MTG32]

Applicable standards set out in Guidance and/or issued by a competent body

- Consistent with standards set by Royal College of Radiology and Society of Coronary Computed Tomography (SCCT). [28]

19.8. Reporting

At the end of each quarter, providers must report back on the following minimum data set:

[28] https://www.rcr.ac.uk/publication/standards-practice-computed-tomography-coronary-angiography-ctca-adult-patients

Report for previous financial year:

- Number of patients scanned with a 64-slide (or above) coronary CT angiography during each quarter of the previous financial year
- A list of the different pathways the site has used for patients presenting with new onset chest pain suggestive of stable angina

Report for each quarter of the current financial year:

- The number of patients scanned with a 64-slice (or above) coronary CT angiography.
- The number of patients receiving a HeartFlow Analysis.
- The number of patients receiving an angiography after a HeartFlow Analysis.

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings:

Year_Quarter_Site name_HeartFlow_Submission date

20. Innovation Specification: SecurAcath - Improved stability/securement and reduced infection risk for patients with a peripherally inserted central catheter

20.1. Purpose

This specification gives NHS providers and commissioners information on SecurAcath, a product included in the Innovation and Technology Payment programme, to secure peripherally inserted central catheters (PICCs).

20.2. Expected Outcome

The expected outcomes from using SecurAcath are a reduction in the number of securement device replacements required and the number of catheter replacement procedures required. This is associated with a lower incidence of catheter-associated complications, such as migration, dislodgement, occlusion, thrombosis and infection. SecurAcath is designed to remain in place as long as the catheter is in place.

20.3. Payment / price detail

The ITP agreed price for SecurAcath is £20 per device and is available under the zero-cost model. NHS Trusts can order SecurAcath directly from the supplier: E-contactus@aquilantservices.com or call 01256 365 490.

20.4. Population Needs

National/local context and evidence base

NICE states that SecurAcath is more effective than adhesive securement devices when a PICC is anticipated to stay in place for 15 days or more.[29] Its analysis suggests that the annual savings from 100 per cent adoption of SecurAcath in these PICC lines is a minimum of £4.2 million a year.[30]

Where a PICC line will remain in place for 25 days or 120 days respectively, the cost savings per patient are estimated to range from £9 to £95.[31]

20.5. Scope

Aims and objectives of the innovation
This innovation aims to:

- Reduce the number of securement device replacements required and lower the number of catheter-associated complications
- Reduce the number of catheter replacement procedures required due to migration or dislodgement

[29] https://www.nice.org.uk/guidance/mtg34/chapter/6-Conclusions
[30] https://www.nice.org.uk/guidance/mtg34/chapter/5-Cost-considerations
[31] https://www.nice.org.uk/guidance/mtg34/chapter/5-Cost-considerations

Innovation description
This innovation is:

- a device which allows subcutaneous attachment of peripherally inserted central catheters (PICC) lines leading to improved stability and reduced infection risk for patients with a PICC
- be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in MTG34

Population covered
This innovation must be appropriate for use in:

- Patients who have an anticipated medium-to long-term dwell time of 15 days or more with a peripherally inserted central catheter, in line with NICE guidance.[32] Through the scope of the ITP, SecurAcath is only funded for PICC lines, not centrally inserted central venous catheters

20.6. Clinical Standards

Acceptance and exclusion criteria and thresholds and site-specific criteria:

- Patients who have an anticipated medium-to long-term dwell time of 15 days or more with a PICC, in line with NICE guidance.[33]
- Through the scope of the ITP, SecurAcath is only funded for PICC lines, not centrally inserted central venous catheters
- Follow the supplier's recommended training plan and available online resources so that all frontline staff are properly trained to be able to correctly insert, maintain and remove SecurAcath, as recommended by NICE
- It should not be used for anyone with a clinically documented nickel allergy
- Pain may be experienced on removal of the device and local anaesthetic may be needed, particularly until staff are fully familiar with the technique
- Infection rates may be increased if the device and catheter are not maintained and dressed according to protocol
- 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
- Initial adverse events may occur, such as skin indentation and anchor migration, until staff becomes familiar with the correct insertion and care techniques

[32] https://www.nice.org.uk/guidance/mtg34
[33] https://www.nice.org.uk/guidance/mtg34

Training by the supplier

Aquilant provides a range of free of charge training platforms, and participation is highly recommended. The training platforms include guidance on correct insertion, care and maintenance and removal of the SecurAcath stabilisation device.

To access these training programs please contact your local Territory Manager or email tenders@aquilantservices.com or T 01256365490.

20.7. Applicable Service Standards

Applicable NICE reviews

- SecurAcath for securing percutaneous catheters: see Medical technologies guidance

20.8. Reporting

At the end of each quarter, providers must report back on the following minimum data set:

Report for previous financial year:

- Number of patients who have PICC lines for more than fifteen days in each quarter of the previous financial year. This is only required for the first report
- Number of complications resulting from catheter dislodgements in each quarter of the previous financial year for patients who had PICC lines for more than fifteen days. This is only required for the first report

Report for each quarter of the current financial year:

- Number of patients who have used SecurAcath during this period of reporting
- Number of complications resulting from catheter dislodgements for patients who have PICC lines for more than fifteen days from this period of reporting

Failure to report quarterly may make your site ineligible for this programme. If you have any questions about the required data please contact england.innovation@nhs.net.

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings:

Year_Quarter_Site name_SecurAcath_ Submission date

21. Innovation Specification: Endocuff Vision ® to improve visualisation of the bowel during colonoscopy by increasing the total surface area of the visual field

21.0. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is included in the Innovation and Technology Payment (ITP) with respect to improved colorectal examination for patients.

21.1. Expected Outcome

The expected outcome is an increase in the adenoma detection rate (ADR) of up to 21% based on the findings from the ADENOMA study[34]. Improved visualisation will enhance the identification of colonic polyps, specifically adenomas and adenocarcinomas, and increase the likelihood of complete excision as well as aiding post-excision scar examination. This will be achieved through improved stability and visualisation provided by Endocuff Vision® during colonoscopy.

21.2. Payment / price detail

The ITP agreed price for Endocuff Vision is £12.05 per device ordered from Norgine Pharmaceuticals via Olympus under the zero-cost model. Providers can email info@olympus.co.uk or call 01702 616 333 to order this product. There is a minimum order of three boxes of Endocuff Vision. More information about Endocuff Vision is available from: http://endocuff.com/products/endocuff-vision.

21.3. Population Needs

National/local context and evidence base

Earlier cancer detection is a priority for the NHS in England. Bowel cancer is the fourth most common cancer in the UK, after breast, prostate and lung cancers. Over 41,000 people are diagnosed with bowel cancer each year. Early diagnosis improves prognosis. Approximately 16,000 people die as a result of bowel cancer in the UK each year, meaning it is the second highest cause of deaths from cancer.[35]

21.4. Scope

Aims and objectives of the innovation
This innovation aims to:

- Improve patient care by improving visualisation to enhance the identification of colonic polyps, specifically adenomas and adenocarcinomas, and increase the likelihood of complete excision as well as aiding post-excision scar

[34] Ngu WS, Bevan R, Tsiamoulos ZP, et al. Improved adenoma detection with Endocuff Vision: the ADENOMA randomised controlled trial. Gut Published Online First: 23 January 2018. doi: 10.1136/gutjnl-2017-314889
[35] https://www.bowelcanceruk.org.uk/about-bowel-cancer/bowel-cancer/

examination. Earlier diagnosis of bowel cancer leads to better patient outcomes and potentially less intensive or invasive management

Innovation description

This innovation must:

- Be a distal device that fits onto the end of a colonoscope, providing improved visualisation and stability during colonoscopy to improve ADR
- Have a class II CE Mark

Population covered

This innovation must be appropriate for use in:

- Patients undergoing colonoscopies who meet the acceptance and exclusion criteria outlined below. It is expected that decisions on use with individual patients are based on the healthcare quality criteria outlined in 11.4.

21.5. Clinical Standards /acceptance and exclusion criteria and thresholds

Acceptance Criteria
NHS sites adopting this technology must:

- Only use Endocuff Vision® attachments with compatible colonoscopes;
- Ensure staff are trained in the correct use of Endocuff Vision®
- Follow instructions for use and use correct Endocuff Vision® size in accordance with the scope being used
- Should not be used for complex sub-mucosal dissection where a separate distal attachment is required

Exclusion Criteria

Sites should be aware that:

- The Endocuff Vision® is not intended for deep ileal intubation
- Should not be used in cases with acute, severe colitis or where there is known colonic stricture

Applicable Service Standards

- Must be consistent with standards set by the Royal College of Physicians Joint Advisory Group on GI Endoscopy
- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in MT509. Expected publication date June 2019

21.6. Reporting

- NHS England is working with Norgine to develop a device registry. Please contact the NHS England Innovation and Research Unit for more information england.innovation@nhs.net.

22. Innovation Specification: Plus Sutures - Reduction of Surgical Site Infection (SSI) through the use of antimicrobial sutures

22.0. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is covered under the Innovation and Technology Payment (ITP) with respect to Triclosan-coated absorbable sutures which are designed to reduce the incidence of surgical site infection (SSIs).

22.1. Expected Outcome

Complications arising from SSIs cost the NHS £700m a year, with a longer expected length of stay putting additional burden on NHS Trusts.[36]

It is anticipated that there will be considerable cost savings as a result of the anticipated reduction in SSIs by up to 30 per cent through using the Plus Sutures. In part this will be realised through a reduction in length of stay by using the sutures. The reported average savings from using antimicrobial sutures is £91.25 per procedure across all wound types.[37]

NHS England has identified Plus Sutures as Triclosan-coated absorbable sutures which currently meets the specification set out in this document. Plus Sutures are an effective way of cutting the incidence of SSIs.

Plus Sutures alone may be expected to reduce infection rates, but they may be more effective when introduced into a specific bundle of measures designed to prevent SSI occurrence.

22.2. Payment / price detail

NHS England will reimburse designated NHS Trusts that transition from standard to Plus Sutures in designated specialties for the 30% premium cost of Plus Sutures, compared to the standard Ethicon sutures. This central reimbursement will be paid on the increased adoption from the initial baseline level at the start of the period. Reimbursement will be made eligible to NHS Trusts which have a baseline SSI rate of 4 per cent or higher, further detail around the baseline criteria is included below.

If the NHS Trusts that adopt Plus Sutures under this ITP programme collectively do not realise a significant reduction in their SSI rate that offsets the additional costs associated with the product then Johnson and Johnson Medical Ltd will reimburse NHS England the difference between the SSI saving achieved and the premium up to a maximum of the total premium incurred by NHS England.
This ensures that an NHS Trust which has a baseline SSI rate of 4 per cent and

[36] https://www.nice.org.uk/guidance/qs49/resources/support-for-commissioning-for-surgical-site-infection-253715293
[37] Wang Z, Jiang C, Cao Y and Ding Y (2012) Systematic review and meta-analysis of triclosan-coated sutures for the prevention of surgical-site infection. British Journal of Surgery 100: 465-473.

above should not have to pay any more for sutures in the specialities set about below than their current Ethicon baseline price or the equivalent baseline price if they are using alternative suture supplier.

Availability: Only sites which meet the 'Site Specification' outlined below will be eligible to have this premium cost covered. Forward enquires to Luke Evans, Platform Manager for Wound Closure, phone 07825 843020 or email levans13@ITS.JNJ.com

22.3. Population Needs

National/local context and evidence base
Surgical site infections cost the NHS £700m a year. SSIs lead to an increased length of stay for patients in hospital. NICE have estimated that the average cost of treating one SSI is £4,300, made up of drugs, dressings, interventions and professional time.[38] NICE estimate that the cost of surgical site infection ranges from £2,100 to £10,500 per infection.[39] Experts have estimated that the cost for complex surgery could be as high as £20,000 per SSI and up to £14,000 for general surgery.[40]

22.4. Site Specification

The following criteria must be met for NHS hospital sites to be funded to purchase Plus Sutures through the ITP. NHS Trusts must have a baseline Surgical Site Infection rate of 4 per cent or above. This is based on data from Hospital Episode Statistics for 2016/2017 for the following specialties: Bariatrics, Breast augmentation, Breast reconstruction, Coronary artery bypass grafting (CABG), Caesarean Section, Cardiac, Colorectal, General Surgery, Gynaecology (not including Hysterectomy), Head and Neck, Hernia, Hepatopancreatobiliary (HPB), Hysterectomy, Neuro, Oncological ablations, Thoracic, Upper Gastrointestinal (UGI), Urology and Vascular.

By targeting NHS Trusts with higher than expected SSIs, the ITP will make the biggest meaningful impact on overall SSI rates which will enable better patient outcomes and cost savings to be realised in the Trusts.

22.5. Scope

Aims and objectives of the innovation
This innovation must:

- Reduce the incidence of Surgical Site Infections using Triclosan-coated absorbable sutures

This innovation must:

[38] https://publications.parliament.uk/pa/cm200809/cmselect/cmpubacc/812/812.pdf

[39] https://www.nice.org.uk/guidance/qs49/resources/support-for-commissioning-for-surgical-site-infection-253715293

[40] https://www.nice.org.uk/guidance/qs49/resources/support-for-commissioning-for-surgical-site-infection-253715293

- Be Triclosan-coated absorbable sutures which are designed to reduce incidence of surgical site infection
- Improve patient care by reducing the incidence of Surgical Site Infections (SSIs)

Population covered
This innovation must be appropriate for use in:

- Patients undergoing the surgical procedures set out in the 'Clinical Standards' section of this guidance document below.

22.6. Clinical Standards

Any acceptance and exclusion criteria and thresholds
NHS England will only reimburse trusts the premium cost of plus sutures when used in the following areas of surgery:

- Bariatrics, Breast augmentation, Breast reconstruction, CABG, Caesarean Section, Cardiac, Colorectal, General Surgery, Gynaecology (not including Hysterectomy), Head and Neck, Hernia, HPB, Hysterectomy, Neuro, Oncological ablations, Thoracic, UGI, Urology and Vascular

22.7. Reporting

- A baseline SSI rate for participating Trusts (those with a 4 per cent SSI rate or above) was produced, based on the procedure and diagnosis codes and specialities as set out above for the 2017/2018 financial year
- NHS England will track the progress of SSI rates based on the procedure and diagnosis codes and specialities set out above on a quarterly basis to track the expected outcomes listed

23. Appendix A: The Academic Health Science Networks (AHSNs) contacts

Location	Contact Name	Email/Telephone
Eastern	Stacie Coburn Chief Operating Officer	E: helen.oliver@eahsn.org T: 01223 661 493
East Midlands	Tim Robinson, Commercial Director	E: tim.robinson@nottingham.ac.uk T: 0115 7484244
Health Innovation Network	Anna King Commercial Director	E: anna.king1@nhs.net T: 0207 188 9805
Health Innovation Manchester	Arjun Sikand Associate Director Commercial Partnerships	E: Arjun.Sikand@healthinnovationmanchester.com T: 0161 206 7978
Imperial College Health Partners	Shirlene Oh Director of Commerce, Innovation and Capability Building	E: Shirlene.oh@imperialcollegehealthpartners.com T: 0333 077 1707
Innovation Agency	Carole Spencer Transformation Director	E: Carole.Spencer@innovationagencynwc.nhs.uk T: 0177 520260
Kent, Surrey and Sussex	Charlotte Roberts Senior Programme Manager	E: charlotte.roberts18@nhs.net T: 0300 303 8660 M: 07818580404
North East and North Cumbria	Nicola Wesley Deputy Chief Executive Officer	E: Nicola.Wesley@ahsn-nenc.org.uk T: 0191 208 1239 M: 07834307906
Oxford	Julie Hart Director of Strategic and Industry Partnerships	E: Julie.hart@oxfordahsn.org T: 07766 775553
South West	Stuart Monk Director of Delivery	E: Stuart.Monk@swahsn.com T: 0139 224 7903
UCLPartners	Robert Berry Head of Innovation	E: robert.berry@nhs.net T: 0300 303 8660
Wessex	Joe Sladen – Associate Director Strategic Programmes	E: joe.sladen@wessexahsn.net T: 07736 896545
West Midlands	Tony Davis Commercial Director	E: tony.davis@wmahsn.org T: 0121 371 8061
West of England	Kay Haughton Director of Service and System Transformation	E: Kay.haughton@weahsn.net T: 0117 900 2192 M: 07557 800886
Yorkshire and Humber	Neville Young Head of Commercial Development	E: neville.young@yhahsn.com T: 0192 466 4506

24. Appendix B: Innovations funded under the ITP and ITT

Funding mechanism	Description	Benefit	Example Product	Nature of funding
ITP 2019/20	A device to allow non-invasive vagus nerve stimulation for the treatment of cluster headaches.	Reduction in cluster headache severity and frequency and improvement in patient quality of life.	gammaCore™	Being funded for national spread
ITP 2019/20	Absorbable spacer to reduce rectum radiation exposure during prostate radiation therapy	Reduction in complications arising from rectal toxicity. Reduced demand across the health system.	SpaceOAR™	Being funded for national spread
ITP 2019/20	A high sensitivity troponin assay for the identification of myocardial infarction	Avoidance of unnecessary hospital admission and reducing unnecessary time-to-discharge, as patients who receive a rapid rule out of a NSTEMI can be directed to more appropriate treatment.	Elecsys Troponin T-hs (TnT-hs)	Being funded for national spread
ITP 2019/20	A diagnostic placental growth factor test for the rule out of preeclampsia in pregnant women	Improved risk assessment for pregnant women with suspected pre-eclampsia. Cost savings through a reduction in bed days and increased clinical staff time.	Roche Elecsys sFlt-1/PlGF ratio test and Quidel Triage PlGF Test - Preeclampsia	Being funded for national spread
EGF 2019/20	Interoperable personal health record	Reduction in fragmented information sharing between health services, health service demand, and paper correspondence.		Funding for specific sites for evidence generation
EGF 2019/20	Digital app to support emergency mental health assessment	Reduction in waiting times for service users for the Mental Health Act, and improved access to specialist doctors.		Funding for specific sites for evidence generation

EGF 2018/19	A patient portal which allows patients to view, manage, reschedule appointments and access information	Provides patients the ability to view and manage their appointments, reduces Did Not Attend (DNA) rates and releases clinic time	DrDoctor	Funding for specific sites for evidence generation
ITP 2018/19	Fractional flow reserve from coronary CT angiography	Rapid diagnosis of patients with suspected Coronary Heart Disease (CAD) using advance image analysis	HeartFlow	Being funded for national spread
ITP 2018/19	Device to allow subcutaneous attachment of PICC lines	Improved stability and reduced infection risk for patients with a peripherally inserted central catheter	SecurAcath	Being funded for national spread
ITP 2018/19	A distal device that fits onto the end of a colonoscope, providing increased flexibility and stability.	Improved colorectal examination for patients undergoing bowel cancer screening	Endocuff Vision	Being funded for national spread
ITP 2018/19	Triclosan-coated absorbable sutures to reduce incidence of surgical site	Reduction of Surgical Site Infection (SSI) through the use of antimicrobial suture packs	Plus Sutures	Uplift cost funded for sites which have a baseline Surgical Site Infection rate of 4 per cent and above.
ITT 2017/18	Guided episiotomy scissors designed to achieve a mediolateral cut at 60 degrees to the perineal midline	Episiotomies successfully cut at the intended 60 degrees minimising the risk of obstetric anal sphincter injuries	Episcissors60	Being funded for national spread
ITT 2017/18	Needle free arterial connecting system with one-way valve	Designed to reduce bacterial contamination and the accidental administration of medication, additionally making blood sampling simple for staff and	Non-injectable arterial connector (NIC)	Being funded for national spread

		improving arterial line safety		
ITT 2017/18	Pneumonia prevention system for intubated patients, a cuffed ventilation tube and electronic cuff pressure controller	Designed to stop leakage of pathogenic oral secretions and stomach contents into the lung, preventing ventilator associated pneumonia (VAP) a leading cause of infective hospital acquired mortality	PneuX	Being funded for national spread
ITT 2017/18	A web-based application for the self-management of chronic obstructive pulmonary disease (COPD)	Aimed at empowering patients to manage their COPD through education, self-management plans and enhanced patient–clinician communication	myCOPD	Funded for national spread in 2017 and 2018.
ITT 2017/18	Frozen Faecal Microbiota transplantation for patients with recurrent Clostridium difficile infection (CDI)	FMT donor samples aim to reduce the risk of repeated CDI relapse, by rebalancing the patient's bowel flora. Donor samples will reduce morbidity and mortality, reduce the risk of avoidable harm and provide an enhanced quality of life for patients	Frozen Faecal Microbiota Transplantation	Being funded for national spread
ITT 2017/18	Prostatic urethral lift system to treat lower urinary tract symptoms of benign prostatic hyperplasia as a day case	Designed as an alternative to current surgical procedures the UroLift® uses adjustable permanent implants to move excessive prostatic tissue away from the urethra, improving symptom control for patients with BPH	UroLift®	Funded under a new OPCS code in the National Tariff for national spread.

25. Appendix C – General Requirements

All innovations must be governed by criteria similar to the Institute of Medicine's six dimensions of healthcare quality[41]. This means that products or services are:

- Safe – avoiding harm to patients wherever possible
- Effective – providing support based on clear benefit to patients
- Efficient – avoiding waste
- Person centred – accepting patient's needs and preferences
- Timely – reduces waits and harmful delays
- Equitable – care does not vary in quality due to patient characteristics

Infection Control

Appropriate infection control measures must be in place and must comply with The Health & Social Care Act 2012 and follow current guidance from the Department of Health and the National Institute for Health & Clinical Excellence.

Safeguarding Children & Vulnerable Adults

Hospitals should have appropriate policies and processes in place to ensure the safeguarding of children & vulnerable adults in compliance with National & local policies and statutory requirements.

Patient records and reporting of episode of care

All clinical records will be clear concise, accurate and legible.

- Systems should be set up within the service so that patients should only need to repeat their registration and case history details for safety and clinical reasons and not because the information cannot be transferred
- Clinical discharge summaries should include:
    - The patient's demographic details and NHS number
    - The patient's presenting condition and diagnosis
    - Details of any diagnostics conducted and where possible, their results
    - Any treatments provided, management plans followed, and any medications prescribed
    - Clinical outcomes
    - Details of any referrals to specialist services to address the patient's immediate needs
    - Any recommendations made to the patient for services to which they might self-refer
    - Any recommendations about appropriate services (including social services) that the GP might wish to refer the patient for their ongoing needs.

[41] Institute of Medicine: Crossing the quality chasm: a new health system for the 21st century. Washington DC: National Academy Press, 1990, p244.

Governance

Operational Governance

Hospitals will be expected to maintain appropriate operational governance arrangements and to undertake regular reviews of operational processes and resolve any problems or issues that arise.

Clinical Governance

Hospitals will be expected to demonstrate that robust clinical governance arrangements are in place. The Trust are expected to maintain registration with the Care Quality Commission and comply with all appropriate national regulatory requirements.

Clinical Standards

Hospitals will be expected to comply with locally agreed clinical standards.

Information Governance

Hospitals will be expected to comply with all local & National Information Governance regulations.

Complaints procedures

Hospitals must operate a complaints procedure which is consistent with the principles of the NHS complaints procedure. Complaints addressed to Hospitals relating to WHCCG patients using the FMT service should, subject to the patient's consent being obtained, be shared with the relevant CCG.

Serious Incidents Requiring Investigation (SIRI)

Hospitals must demonstrate robust arrangements for recording and investigating SIRIs. All SIRIs involving patients must be reported to the relevant Clinical Commissioning Group.

Legal Protection

The service provider must demonstrate that they are appropriately indemnified to meet the costs of any legal claim by having full indemnity and liability insurances in place.