SCHEDULE 2 – THE SERVICES

A. Service Specifications

This is a non-mandatory model template for local population. Commissioners may retain the structure below or may determine their own in accordance with the Contract Technical Guidance.

Service Specification No.	
Service	Universal Offer – Intrauterine System (IUS) for Menorrhagia
Commissioner Lead	Mel Mahon, Head of Primary Care Commissioning, Staffordshire and Stoke-on-Trent CCGs
Provider Lead	
Period	1st October 20 – 30th September 24 4 years with a six month notice period for termination. The service specification will be subject to regular review.
Date of Review	1st October 21 and annually thereafter

1. Population Needs

1.1 National/local context and evidence base

Evidence shows that IUS has the additional non-contraceptive benefits of decreasing menstrual loss and is part of the management of menorrhagia recommended by the Royal College of Obstetricians and Gynaecologists (RCOG).

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	
Domain 2	**Enhancing quality of life for people with long-term conditions**	
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**X**
Domain 4	**Ensuring people have a positive experience of care**	**X**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

2.2 Local defined outcomes

3. Scope

3.1 Aims and objectives of service

- Service Users have access IUS coil fitting in the management of menorrhagia within primary

care.

- To reduce the number of secondary care referrals to Gynaecology for IUS coil fittings for the clinical indication of menorrhagia

3.2 Service description/care pathway

- To provide a fitting, checking and removal service where the IUS coil has been indicated in the treatment of menorrhagia.
- The Provider shall undertake an initial telephone consultation for patients referred to the service. This will include assessment, patient history and counselling of side effects and consequences of treatment with a clear opportunity for patients to ask questions about IUS
- The Provider shall fit, follow up and remove the IUS as appropriate. Only practitioners who hold a current Letter of Competence in intrauterine techniques will be able to provide the service
- The Provider shall advise women as to signs and symptoms of infection, perforation and expulsion
- The Provider shall undertake an assessment of the fitting and a routine follow-up visit can be advised after the first menses following insertion of IUS or 3-6 weeks later. The provider shall undertake the 6 week follow up assessment by telephone in the first instance, with face to face review taking place when required
- Any problems such as abnormal bleeding or pain should be assessed as a matter of urgency by the patient's GP if acute
- The Provider shall ensure written information has been provided to the patient at the point of referral, time of counselling and reinforced after fitting. Information shall include follow-up procedures and those symptoms that require urgent assessment
- An assessment for STI risk and swab where clinically indicated (as per FSRH guidance) should be undertaken by the referring GP prior to the referral being made and before the referral is accepted by the Provider. In the event a patient attends for an IUS insertion and the provider suspects there may be an STI risk, FSRH guidance must be adhered to.
- The Provider shall gain written consent from the patient prior to insertion
- The Provider shall produce and maintain an up to date register of all patients fitted with an IUS device. This needs to include:
  - ❖ Name of the patient
  - ❖ NHS number
  - ❖ Date of birth
  - ❖ Device fitted
  - ❖ Batch number
  - ❖ Expiry date,
  - ❖ Name & designation of the person completing the procedure

The register will also record if there were any problems with the insertion/removal and any follow up actions and referrals to other services.

- The Provider shall ensure that the service is delivered from approved practice premises with the provision of adequate equipment. Equipment required for the IUS fitting includes an appropriate room fitted with a couch and with adequate space and equipment for resuscitation (as required within GP practices). A variety of vaginal specula, cervical dilators, and any other appropriate equipment also needs to be available

Sterilisation & Infection prevention control: Although LARC procedures have a low incidence of complication, it is important that practices providing the procedures listed in this specification operate to the highest possible standards. Practices must use one of the following arrangements for sterilisation:

- Disposable sterile instruments
- Sterile packs/instruments
- Approved sterilisation procedures that comply with national guidelines as needed

3.3 Population covered

The service is available to patients registered with the GP practice or to another practice within the Primary Care Network.

3.4 Any acceptance and exclusion criteria and thresholds

The following exclusion criteria apply:

- Women who wish to have this treatment for heavy menstrual bleeding as first line following careful assessment and examination (as per NICE HMB) to exclude pathology
- Women who have red flags i.e. symptoms that suggest a more sinister pathology requiring urgent investigation

- The use of IUS is solely for the treatment of menorrhagia and contraceptive indications is outside the scope of this service. IUS can be used where there is a dual diagnosis, i.e. endometrial protection for patients prescribed hormone replacement therapy.

Before a patient is referred to this service the registered GP will have:

- Discussed the most appropriate method of treatment with the patient based on medical evidence and clinical guidelines
- Arranged Ultrasound Scan if an abdominal examination suggests a mass, pressure, urge incontinence / urinary frequency or a difficult examination
- Recorded the information in the patients record

3.5 Interdependence with other services/providers

The Provider shall ensure that, where appropriate to the service, interdependencies are built with the following service providers:

- Acute Service
- Community Services
- Voluntary Sector Organisations
- Advocacy Services
- NHS England

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

- Heavy Menstrual Bleeding: http://www.nice.org.uk/nicemedia/pdf/CG44FullGuideline.pdf

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

- Best practice should be followed for the insertion of intrauterine device as outlined in The Faculty of Sexual and Reproductive Health care clinical guidance on intrauterine contraception 2015, amended 2019 https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/

- Resuscitation guidelines are adhered to: https://www.fsrh.org/documents/service-standards-for-resuscitation-in-sexual-and-reproductive/service-standards-for-resuscitation-in-sexual-and-reprdocutive-healthcare-services-august-2016.pdf

4.3 Applicable local standards

The Provider will ensure:

- 100% of practitioners providing the service to hold current FRSH (or RCN) Letters of Competence in Intrauterine Techniques (LoC IUT)
- Each practitioner providing this service to have completed at least 12 insertions per annum (If GPs are providing IUCD/IUS services with another commissioner, the practice can count those procedures towards the minimum requirement per year)
- The Provider shall ensure the patient has undertaken all relevant examinations prior to a accepting the referral

- The Provider shall ensure the patient waits no longer than 6 weeks following referral for an IUS (as long as all appropriate examinations have been completed) and:
  - Will need to ensure the patient is appropriately counselled about timing of cycle/bridging contraception
- The Provider shall be able to demonstrate the delivery of patient choice when any referral to secondary care is necessary following consultation
- The Provider shall discharge the patient back to the referring GP following the 6 week review. The Provider shall be responsible for ensuring the referring GP is sent a comprehensive typed summary letter outlining advice for on-going care

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4A-C)

5.2 Applicable CQUIN goals (See Schedule 4D)

6. Location of Provider Premises

The Provider's Premises are located at:

The service is to be delivered from the GP practice or from another practice or appropriate healthcare setting within the Primary Care Network (PCN) where the practice is providing on behalf of the PCN.

SCHEDULE 2 – THE SERVICES

A. Service Specifications

This is a non-mandatory model template for local population. Commissioners may retain the structure below or may determine their own in accordance with the Contract Technical Guidance.

Service Specification No.	*Numbering the specification may be useful where you wish to identify which services particular quality requirements and/or payment regimes relate to.*
Service	Universal Offer - ECG
Commissioner Lead	Mel Mahon, Head of Primary Care Commissioning, Staffordshire and Stoke-on-Trent CCGs
Provider Lead	
Period	1st October 20 – 30th September 24 4 years with a six month notice period for termination. The service specification will be subject to regular review.
Date of Review	1st October 21 and annually thereafter

1. Population Needs

1.1 National/local context and evidence base

The service delivers ECG diagnostic testing to check the heart's rhythm and electrical activity. Without ECG testing, cardiology conditions such as arrhythmias, electrolyte disturbances and heart block/conduction problems would not be effectively diagnosed. This could lead to patients not receiving appropriate treatment for the condition, resulting in exacerbations and acute attendances with an impact on patient quality of life. There may also be incidences where patients may be treated for various cardiology conditions without a diagnosis as they have symptoms representative of cardiology problems resulting in avoidable interventions.

ECG provides an objective measurement of the electrical activity of the heart. It measures the depolarisation and repolarisation of the atria and ventricles, indicating the rate and rhythm of the heartbeat, the presence of any damage to the tissues of the heart or the effects of any drugs on the heart.

By using ECG to assess heart function it is possible to diagnose arrhythmias and heart block with greater confidence and accuracy and is vital for assessing the severity of cardiac disturbances.

The Universal Offer ECG service will deliver care to patients in GP Practices, provide timely identification of rhythm abnormalities and avoid unnecessary referrals to secondary care, in line with national policy.

The expectation is that the majority of direct GP referred outpatient ECGs can take place in a more convenient location for patients offering improved access and enhanced continuity of care.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	**X**
Domain 2	**Enhancing quality of life for people with long-term conditions**	

Domain 3	**Helping people to recover from episodes of ill-health or following injury**	
Domain 4	**Ensuring people have a positive experience of care**	**X**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	

2.2 Local defined outcomes

The delivery of ECGs in primary care will support the move of activity where clinically appropriate to primary and community settings.

3. Scope

3.1 Aims and objectives of service

The aim of this service is to:

- Enable the early identification of patients with cardiac conditions and subsequent management of these patients within primary care.
- Reduce demand and waiting times for secondary care ECG services.
- Provide a report which will enable an improvement in the quality of GP referral or the management of patient care in the community.
- Provide patients with rapid access to diagnostics and treatment of cardiac symptoms in a setting that is close to home.

3.2 Service description/care pathway

- Undertaking of a 12-lead ECG by suitably trained Healthcare worker
- The printing out (or uploading digitally) of an ECG tracing for interpretation by a qualified Healthcare Professional.
- Interpretation of the ECG tracing remains the responsibility of the referring clinician who should not rely unduly on any computerised interpretation.

3.3 Population covered

Patients registered with a GP practice in the Staffordshire and Stoke-on-Trent CCGs (including temporary patients)

3.4 Any acceptance and exclusion criteria and thresholds

Inclusion criteria:

- Patients who are referred to the service by the GP where an ECG is clinically indicated.

Exclusion criteria:

- Patients not registered with a GP in the Staffordshire and Stoke-on-Trent CCGs area.
- Patients unwilling or likely to be unable to be compliant with the service.
- ECGs required for routine medicals and medical certificates.
- ECGs are not to be performed as part of a pre-operative assessment.
- ECGs required as part of medication initiation or review or disease monitoring where the prescriber or clinician managing the condition is not the GP

Patients with clinical symptoms including any of the following conditions should be sent to hospital:

- Suspected acute Myocardial infarction (MI).
- Acute or unstable angina.

- Suspected complete heart block
- Tachyarrhythmia in an unwell patient such as Atrial Fibrillation with a rate over 150 or clinically compromised

3.5 Interdependence with other services/providers

The provider shall ensure that, where appropriate, interdependencies are built with the following service providers:

- acute services
- community providers
- advocacy services.

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

NICE guidance & NCGC guidelines for Acute Chest Pain & suspected ACS including 12-lead ECGs., taking into account clinical judgement.

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

All practice nurses/healthcare assistants must be appropriately trained in taking an ECG and take into consideration their professional accountability to the Nursing and Midwifery Council guidance on the scope of professional practice.

4.3 Applicable local standards

Equipment

All costs associated with the purchase and maintenance of equipment required to provide this service will be borne by the provider. The provider must ensure that the 12-lead ECG machine is maintained annually by means of an accredited contract with an approved supplier. Details of the annual maintenance contract and last servicing date of equipment must be provided to the CCG.

Appropriate arrangements must be made for the maintenance and safety checks of the ECG machines according to the manufacturer's schedule. A copy of proof that the appropriate maintenance (PAT testing) and safety checks of the ECG machines has been carried out in accordance with the manufacturer's schedule is to be stored for the CCG inspection. Details of equipment specifications are available from: The Society of Cardiology Science & Technology, the British Cardiovascular Society or other relevant experts.

Training and Competencies

The service will be provided by a healthcare worker who is competent in the use and recording of an ECG.

Those doctors and healthcare workers who have previously provided services similar to this enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.

There must be evidence that non medically trained practitioners have received training and are competent to undertake ECG monitoring

The provider must ensure that there is appropriate support and supervision available for those providing the service.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4A-C)

5.2 Applicable CQUIN goals (See Schedule 4D)

6. Location of Provider Premises

The Provider's Premises are located at:
The service shall be delivered from the GP practice or branch surgery of the delivering GP practice or from another healthcare setting within the delivering Primary Care Network.

SCHEDULE 2 – THE SERVICES

A. Service Specifications

This is a non-mandatory model template for local population. Commissioners may retain the structure below or may determine their own in accordance with the Contract Technical Guidance.

Service Specification No.	*Numbering the specification may be useful where you wish to identify which services particular quality requirements and/or payment regimes relate to.*
Service	Universal Offer – Phlebotomy
Commissioner Lead	Mel Mahon, Head of Primary Care Commissioning, Staffordshire and Stoke-on-Trent CCGs
Provider Lead	
Period	1st October 20 – 30th September 24 4 years with a six month notice period for termination. The service specification will be subject to regular review.
Date of Review	1st October 21 and annually thereafter

1. Population Needs

1.1 National/local context and evidence base

The service is designed to cover the requirement for the provision of a primary care phlebotomy service being provided over and above the essential and additional services that General Medical Service (GMS) are contracted to provide.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	
Domain 2	**Enhancing quality of life for people with long-term conditions**	**X**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**X**
Domain 4	**Ensuring people have a positive experience of care**	**X**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

2.2 Local defined outcomes

3. Scope

3.1 Aims and objectives of service

- Provide a timely service for phlebotomy related conditions in a primary care setting
- Satisfy local demand from patients
- To deliver the shortest pathway possible, compatible with best outcomes for patients
- Improve the monitoring and management of Long Term Chronic illness

3.2 Service description/care pathway

Under the provision of Primary Care Universal Offer phlebotomy services:

- The Provider shall provide phlebotomy services for patients within the GP practices / Primary Care Network that are initiated within general practice.

3.3 Population covered

The service is available to patients registered with the GP practice or to another practice within the Primary Care Network (PCN) where the practice is providing on behalf of the PCN

3.4 Any acceptance and exclusion criteria and thresholds

Under the conditions of this agreement, the provider has the responsibility to ensure that:

The service is to be available to all patients meeting the following criteria:

- Registered practice patients / patients from a practice within the Primary Care Network
- Able to attend surgery premises

The service does not include

- Patients on a secondary care 2WW/urgent pathway where a blood test is deemed clinically appropriate
- Patients within a secondary care outpatient clinic where a blood test is deemed clinically appropriate
- Patients under the care of Accident & Emergency
- Inpatients
- Patients from whom venepuncture is difficult
- Patients who choose to attend secondary care for blood sampling procedure
- Children under the age of 14
- Tertiary care phlebotomy
- Specialist commissioning phlebotomy
- Secondary care initiated phlebotomy
- INR testing
- Domiciliary bloods

The Universal Offer phlebotomy service specification and available funding is for the provision of primary care initiated bloods however providers wishing to maintain delivery of current phlebotomy services within their practices should ensure that quality, accreditation and clinical governance requirements are in place to ensure patient safety and monitoring and action of results.

3.5 Interdependence with other services/providers

The provider shall ensure that, where appropriate to the service, interdependencies are built with the following service providers:

- Acute Service
- Community Services
- Advocacy Services

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

Any healthcare professional who is involved in performing or assisting in any procedure has the evidence of necessary experience, skills and training with regards to said procedure, as a minimum to

the levels described in the National Occupational Standard HSC376 training (www.skillsforhealth.org.uk), which includes a period of mentorship.

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

The Provider will ensure:

- The recommendations in the NMC Code of Conduct (2008) Royal College of Nursing Competency framework for capillary blood sampling and venepuncture are followed.

4.3 Applicable local standards

Under the conditions of this agreement, the Provider has the responsibility to ensure that:

- Appropriate arrangements are in place for infection control and decontamination in premises where these procedures are undertaken. The provider must have infection control policies that are compliant with national guidelines
- The Provider must have a protocol for needle-stick injury management
- The provider will ensure that the services are carried out in approved premises and facilities are in place to enable them to provide the phlebotomy service properly
- The provider shall be expected to work and liaise with secondary care providers for referral into their services where required.
- The provider shall have in place mechanisms for the transfer of patients suffering complications of the procedure.
- The staff undertaking the procedure must have verified Hep. B protection.
- Staff undertaking the procedure must have suitable indemnity.
- Practices must adhere to good practice as outlined in the Infection Control Guidance for General Practice [RCGP/CICNN document, issued to all practices December 2003]
- The practice must maintain a stock of suitable phlebotomy containers and ensure the correct usage. These should be ordered from the Pathology department
- Blood samples must be stored in a safe clinical environment prior to transportation to the Pathology Department
- Samples must be transported via the CCG funded courier service to ensure a safe delivery and quality condition of the samples.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4A-C)

5.2 Applicable CQUIN goals (See Schedule 4D)

6. Location of Provider Premises

The Provider's Premises are located at:

The service is to be delivered from the GP practice or from another practice or appropriate healthcare setting within the Primary Care Network (PCN) where the practice is providing on behalf of the PCN.

SCHEDULE 2 – THE SERVICES

A. Service Specifications

This is a non-mandatory model template for local population. Commissioners may retain the structure below or may determine their own in accordance with the Contract Technical Guidance.

Service Specification No.	
Service	Universal Offer – Gonadarelin Administration
Commissioner Lead	Mel Mahon, Head of Primary Care Commissioning, Staffordshire and Stoke-on-Trent CCGs
Provider Lead	
Period	1st October 20 – 30th September 24 4 years with a six month notice period for termination. The service specification will be subject to regular review.
Date of Review	1st October 21 and annually thereafter

1. Population Needs

1.1 National/local context and evidence base

The administration of gonadorelins within primary care is designed to be an enhanced service in which patients with an established diagnosis and agreed treatment plan for carcinoma of the prostate, carcinoma of the breast, preoperatively for women having hysterectomy, and for use in patients with fibroids or endometriosis, can undergo part of their treatment safely, effectively and conveniently close to their home.

The administration of gonaderelins for use in precocious puberty, assisted reproduction and gender identification disorder/dysphoria are not included within this service.

2. Outcomes

2.1 <u>NHS Outcomes Framework Domains & Indicators</u>

Domain 1	**Preventing people from dying prematurely**	**X**
Domain 2	**Enhancing quality of life for people with long-term conditions**	**X**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**X**
Domain 4	**Ensuring people have a positive experience of care**	**X**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

2.2 Local defined outcomes

- The Provider shall offer a patient-focused and easily accessible service with timely access to an appointment.

3. Scope

3.1 Aims and objectives of service

- The Provider shall support the administration of androgen deprivation administration in order to support delivery in primary care for improved patient care closer to home.

- The Provider shall provide a service designed, with trained staff and appropriate facilities, to ensure sufficient resources are available in primary care to deliver services in a sustainable and clinically accountable fashion.

3.2 Service description/care pathway

The Provider shall administer of one of the following gonaderelins for a licensed indication of the product as listed in section 3.2.1.:

- Goserelin (Zoladex® 3.6 mg implant and Zoladex® LA 10.8 mg)
- Leuprorelin (Prostap® 3 DCS and Prostap® SR DCS)
- Triptorelin (Decapeptyl® SR 3mg, Decapeptyl® SR 11.25mg, Decapeptyl® SR 22.5mg)

Information on the licensed indications of these drugs is provided in appendix 1 however the most up-to-date product Summary of Product Characteristics (SmPC) is the most complete source of information.

Patients should remain under specialist care for management of their condition and advice on dose changes or discontinuation of treatment will be provided to the Contractor.

It is a requirement of this Local Enhanced Service that the Provider:

- Provides a register - The Contractor will need to produce and maintain a valid up-to-date register of patients being treated as part of this enhanced service.
- Demonstrates a call and recall system - The Contractor will need to ensure a systematic call and recall of patients on this register is taking place, and have in place the means to identify and follow up patients in default.
- Support the education of both newly diagnosed patients and those with established disease - The secondary care specialist teams will provide the main source of advice for both newly diagnosed patients and those with established disease. The Contractor will reinforce and supplement that advice where appropriate to do so.
- Maintains accurate records – The Contractor is to maintain adequate records of the service provided, incorporating all known information relating to any significant events e.g. adverse reactions, hospital admissions and relevant deaths of which the practice has been notified.
- Ensures individual management plans are in place – Clear treatment/individual management plans should be provided by the specialist which detail the indication, agreed treatment programme and the planned duration of treatment. The Contractor should ensure these are documented in the patients' medical records.
- Ensure primary care staff training - The Contractor must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so. Practices should be able to demonstrate that they have in place a policy to cover staff training and maintenance of skills which includes a register of trained staff to administer androgen deprivation treatments under this service.

3.3 Population covered

The service is available to patients registered with the GP practice or to another practice within the Primary Care Network.

3.4 Any acceptance and exclusion criteria and thresholds

The service is to be available to all patients meeting the following criteria:

- Registered practice patients
- Able to attend surgery premises
- Who have an indication for androgen deprivation therapy as detailed in section 3.2.

The administration of gonaderelins for use in precocious puberty, assisted reproduction and gender identification disorder/dysphoria are not included within this service.

3.5 Interdependence with other services/providers

The Provider shall ensure that, where appropriate to the service, interdependencies are built with the following service providers:

- Acute Service
- Community Services
- Voluntary Sector Organisations
- Advocacy Services
- NHS England

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

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

Summary of Product Characteristics (SmPC) is to be used for information on the licensed indications of these drugs.

4.3 Applicable local standards

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4A-C)

5.2 Applicable CQUIN goals (See Schedule 4D)

6. Location of Provider Premises

The Provider's Premises are located at:

The service is to be delivered from the GP practice or from another practice or appropriate healthcare setting within the Primary Care Network (PCN) where the practice is providing on behalf of the PCN.

Appendix 1: Licensed indications for gonaderelin preparations *Information correct at 04/11/2019. For the most up-to-date licensing information please refer to each products' Summary of Product Characteristics (SmPC) available on the Electronic Medicines Compendium (eMC) (www.medicines.org.uk).*

Drug	Goserelin		Leuprorelin		Triptorelin		
Product	**Zoladex 3.6mg Implant**	**Zoladex LA 10.8mg Implant**	**Prostap SR DCS (3.75mg)**	**Prostap 3 DCS (11.25mg)**	**Decapeptyl SR 3mg**	**Decapeptyl SR 11.25mg**	**Decapeptyl SR 22.5mg**
Administration interval	Monthly	3 monthly	Monthly	3 monthly	Monthly	3 monthly	6 monthly
Prostate cancer indications:							
Metastatic prostate cancer	✓	✓	✓	✓	✓	✓	✓
Locally advanced prostate cancer, as an alternative to surgical castration.	✓	✓	✓	✓	✓	✓	✓
Adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.	✓	✓	✓	✓	✓	✓	✓
Neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.	✓	✓	✓	✓	✓	✓	✓
Adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression.	✓	✓	✓	✓	✓	✓	✓
Breast cancer indications:							

Advanced breast cancer in pre and perimenopausal women suitable for hormonal manipulation.	✓		✓	✓			
Alternative to chemotherapy in the standard of care for pre/perimenopausal women with oestrogen receptor (ER) positive early breast cancer.	✓						
As adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in women at high risk of recurrence who are confirmed as pre-menopausal after completion of chemotherapy			✓ (recommended max. 5 years treatment)	✓ (recommended max. 5 years treatment)	✓ (recommended max. 5 years treatment)		
Preservation of ovarian function in pre-menopausal women with neoplastic disease undergoing chemotherapy treatment that can cause premature ovarian insufficiency.			✓				
Endometriosis:							
Treatment of endometriosis.					✓ (max. 6 months treatment)	✓ (max. 6 months treatment)	
Management of endometriosis, including pain relief and reduction of endometriotic lesions.	✓ (max. 6 months treatment)		✓ (max. 6 months treatment)	✓ (max. 6 months treatment)			

Endometrial preparation prior to intrauterine surgical procedures including endometrial ablation or resection.	✓ (max. 8 weeks treatment)		✓ (single dose 5-6 weeks prior to surgery)				
Uterine fibroids:							
Preoperative management of uterine fibroids to reduce their size and associated bleeding.			✓ (max. 6 months treatment)				
Treatment of uterine fibroids prior to surgery or when surgery is not appropriate.					✓ (max. 6 months treatment)		
Uterine fibroids: In conjunction with iron therapy in the haematological improvement of anaemic patients with fibroids prior to surgery.	✓ (max. 3 months treatment prior to surgery)						
Other indications (administration not included within this Local Enhanced Service):							
Assisted reproduction: Pituitary downregulation in preparation for superovulation.	✓						
Treatment of precocious puberty (onset before 8 years in girls and 10 years in boys).						✓	
Treatment of central precocious puberty (CPP) in children 2 years and older with an onset of CPP before 8 years in girls and 10 years in boys).							✓

SCHEDULE 2 – THE SERVICES

A. Service Specifications

This is a non-mandatory model template for local population. Commissioners may retain the structure below or may determine their own in accordance with the Contract Technical Guidance.

Service Specification No.	
Service	Universal Offer – Primary Care Wound Care
Commissioner Lead	Mel Mahon, Head of Primary Care Commissioning, Staffordshire and Stoke-on-Trent CCGs
Provider Lead	
Period	1st October 20 – 30th September 24 4 years with a six month notice period for termination. The service specification will be subject to regular review.
Date of Review	1st October 20 and annually thereafter

1. Population Needs

1.1 National/local context and evidence base

The service is required to provide simple wound care to ambulatory patients in order to reduce a patients need to attend hospital and therefore release secondary care resources appropriately and to remove sutures in primary care that have been inserted in secondary care.

2. Outcomes

2.1 <u>NHS Outcomes Framework Domains & Indicators</u>

Domain 1	**Preventing people from dying prematurely**	
Domain 2	**Enhancing quality of life for people with long-term conditions**	
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**X**
Domain 4	**Ensuring people have a positive experience of care**	**X**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

2.2 Local defined outcomes

To provide a wound care service in Primary Care for patients registered with the practice or Primary Care Network.

3. Scope

3.1 Aims and objectives of service

To provide a service that delivers simple wound care to registered patients of a practice, and to deliver routine post-operative or post-treatment suture removal and simple wound care services to registered patients of the practice upon discharge from hospital, after a surgical procedure, to include suture or clip removal and, when necessary, subsequent cleansing and dressing of wounds.

For the purpose of this specification the definition of Simple Wound Care is set out below:
Simple wound – when the wound is superficial that is, involving primary epidermis or dermis, or subcutaneous tissues without significant involvement of deeper structures and requires simple one layer bandaging/dressing.

Ambulatory – Patients who are physically able (with or without assistance) to access clinic, minor injury unit or GP practice/walk in centre.

3.2 Service description/care pathway

Under the provision of wound care services:

- The Provider shall deliver simple wound care, excluding treatment of leg ulcers
- The Provider shall provide suture removal and application of any associated dressings following a minor surgical procedure resulting in a wound that meets the criteria within this specification (see wound care definition)

The Provider shall:

- Offer this service for all registered patients
- Provide simple wound care for ambulatory patients (Children and Adults)
- Provide simple wound care for ambulatory patients (Children and Adults) following a minor surgical procedure including post-operative suture removal for patients. The term suture includes: stitches, staples and clips
- Deliver wound care assessment and treatment using evidence-based wound care management
- Support self-management of wounds and provide relevant information to patients to facilitate this
- Refer housebound patients to the community service provider. Where wound care for housebound patients is referred to the GP Provider when not appropriate, it is the responsibility of the referrer to redirect the referral of the patient to the Community Team not the GP Provider
- Use agreed local formulary for dressings and bandages
- The Provider (GP practice) shall undertake to refer patients when appropriate promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist

The Provider will ensure:

- All staff delivering the post-operative wound care service adhere to infection control appropriate to primary and community care, are appropriately trained and competent to assess the wound, to escalate for further treatment, where indicated, and apply appropriate wound dressing where indicated.
- Practitioners undertaking suture removal under this service shall have had training in surgical environments or been taught and assessed as competent by an appropriately experienced clinician.

3.3 Population covered+

The service is available to patients registered with the GP practice or to another practice within the Primary Care Network (PCN) where the practice is providing on behalf of the PCN

3.4 Any acceptance and exclusion criteria and thresholds

The service is to be available to all patients meeting the following criteria:

- Registered practice patients
- Able to attend surgery premises
- Patients requiring simple wound care including following surgical procedures

The service does not include

- Complex wound care or wound care for house bound patients
- Treatment of leg ulcers

3.5 Interdependence with other services/providers

The provider shall ensure that, where appropriate to the service, interdependencies are built with the following providers:

- Community nursing services
- Acute service

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

Under the conditions of this agreement, the Provider has the responsibility to ensure that:

- The service will maintain a safe and suitable environment for patients and staff and comply with all relevant statutory governance requirements, legislation, Department of Health Guidance, Professional Codes of Practice, Standards for Better Health, NICE guidance 'Healthcare-associated infections: prevention and control in primary and community care', March 2012 –updated February 2017.
- (https://www.nice.org.uk/guidance/CG139) and all Health and Safety regulations

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

4.3 Applicable local standards

- Use of the agreed local formulary for dressings and bandages

Under the conditions of this agreement, the provider has the responsibility to ensure that:

- Practitioners undertaking suture removal should have had training in surgical environments or been taught and confirmed as competent by an experienced clinician

5. Applicable quality requirements and CQUIN goals

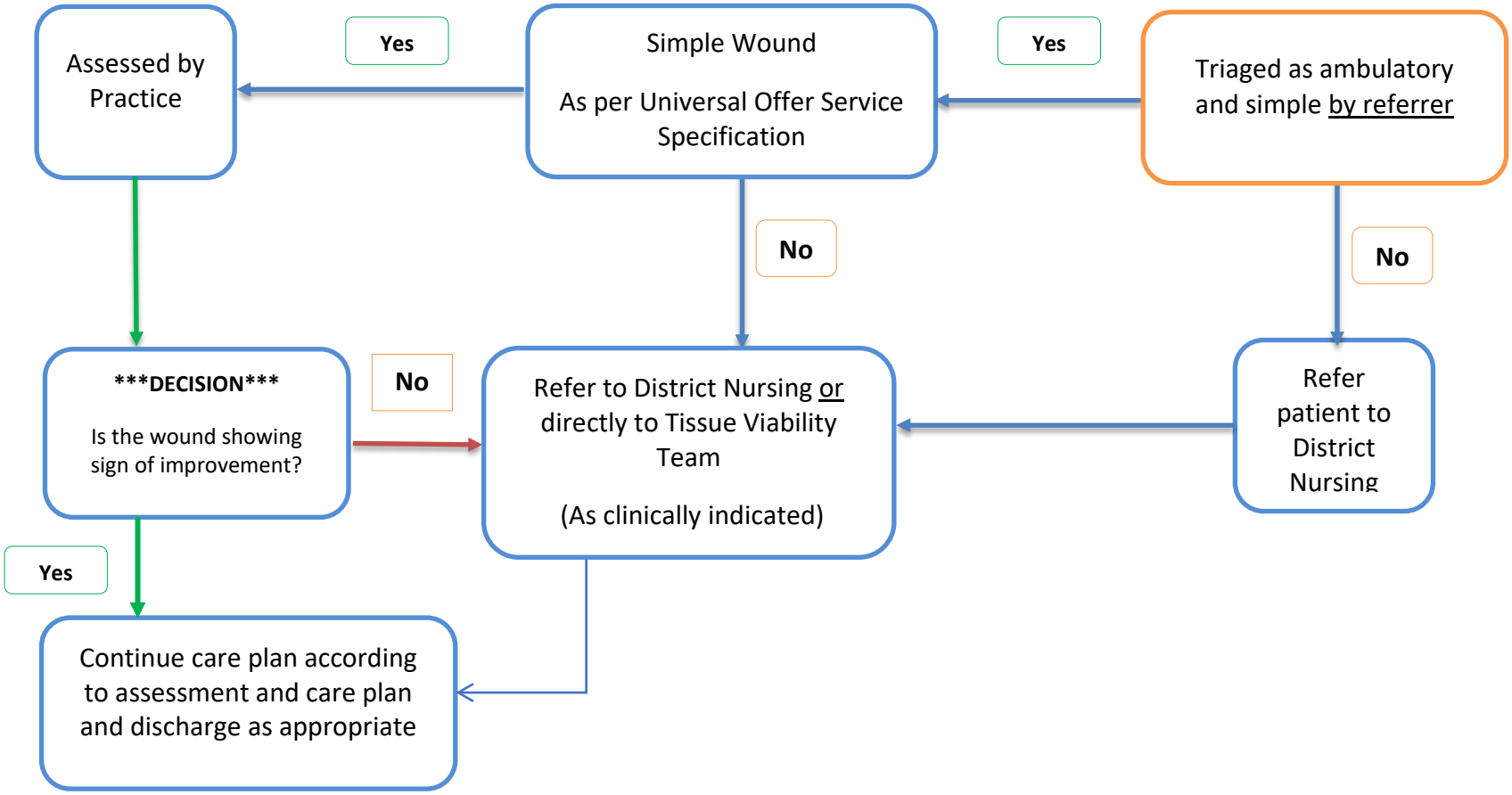
5.1 Applicable Quality Requirements (See Schedule 4A-C)

5.2 Applicable CQUIN goals (See Schedule 4D)

6. Location of Provider Premises

The Provider's Premises are located at:

The service is to be delivered from the GP practice or from another practice or appropriate healthcare setting within the Primary Care Network (PCN) where the practice is providing on behalf of the PCN



Note: The patient remains with the provider – either district nurse or GP practice until the episode is complete.

Guidance Sheet	
What is a Simple Wound?	Simple wound are wounds involving only the skin and not the deeper structures, no drains and no packing.
Examples of a simple wound	These are wounds that may require suture/clip removal but should be healed within a few weeks. They may include abrasions and first degree burns/scalds but not leg ulcers or pressure sores.
Are minor procedures included?	They do not include removal of sutures from procedures where a body cavity has been opened or a joint replaced.
Where do I refer complex woundcare?	All other wound care should be referred to the district nursing service or tissue viability. Prescriptions for wound care should be from the agreed wound care formulary green section
What about the housebound Patients?	Wound care will be provided in the surgery only. Patients requiring care in their own home will be the responsibility of the district nursing service.
What if the wound is not improving?	Any wound that does not heal within a few weeks period should be classed as complex and referred to the district nursing service who may choose to involve tissue viability or other specialist services if appropriate.
What about the infected wound?	Prescribe from amber section of formulary for two weeks only and an exemption form to be completed and forwarded to Medicines Management Team.

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	
Service	Spirometry and Assessment Service (Diagnosis Only)
Commissioner Lead	
Provider Lead	
Period	TBC Post Covid Guidance
Date of Review	Annually by 31st March each year

1. Population Needs

1.1 National/local context and evidence base

National context

2.1 million people are living with undiagnosed COPD which is an estimated 70% of the total number of people with COPD. Of the undiagnosed population, the majority have mild or moderate disease, but a significant minority have severe COPD. Conversely over 25% of people with a diagnostic label of COPD have been wrongly diagnosed, usually because of poorly-performed spirometry. Similarly for Asthma it is estimated that 30% of patients with a diagnosis have no clear signs of asthma.

COPD causes around 30,000 deaths in England each year, with one person dying from the condition every 20 minutes. Co-morbidities such as heart disease, cancer, osteoporosis and depression are common at all stages of COPD, and are often diagnosed late. Patients with COPD are also at a much higher risk of premature death from heart disease and stroke.

Nationally 10% of emergency COPD admissions are in people whose COPD has not previously been diagnosed. If people remain undiagnosed until they are severely disabled by the condition, or are admitted to hospital as an emergency, the benefits of treatment to the individual are greatly reduced and the costs to the healthcare system greatly increased.

Several publications at a national level have recommended earlier and accurate diagnosis of COPD / Asthma via quality-assured spirometry.

The *Outcomes Strategy for COPD and Asthma* and the subsequent *NHS Companion Document to the Strategy* suggested the NHS could:

- perform quality-assured diagnostic spirometry on those identified and confirm diagnosis, together with other investigations to assess severity and coexistence of other conditions

The *NICE Clinical Guideline for COPD* highlights diagnosis as a priority for implementation, recommending:

- that people have an appropriate diagnosis of COPD confirmed by an competent professional performing spirometry

The *NICE Quality Standard for COPD* also highlights the importance of diagnosis through quality-assured spirometry:

- Quality Statement 1: People with COPD have one or more indicative symptoms recorded, and have the diagnosis confirmed by post-bronchodilator spirometry carried out on calibrated equipment by healthcare professionals competent in its performance and interpretation.

The *Guide to Performing Quality Assured Diagnostic Spirometry 2013* states that

- To be valid spirometry that is used for diagnosis must be quality assured and should only be performed by people who have been trained and assessed to ARTP or equivalent standards by recognised training bodies in the performance and interpretation of spirometry.

As a consequence of this guide all healthcare professionals must be on the National Register of certified healthcare professionals in order to perform diagnostic spirometry.

Local Context

Staffordshire and Stoke on Trent CCGs have a combined total of c1m patients registered with a general practice. Whilst spirometry services are currently available across the region there is variation in the level of service provided; with some provided via Primary Care and others through a Community or acute provision.

The RightCare programme identified Respiratory as one of the largest areas of opportunity for our local health economy; as a consequence of this there is increased focus on the management and identification of patients.

Whilst the number of patients on the COPD and Asthma register has steadily increased over previous years a significant number of the Staffordshire and Stoke on Trent CCG areas have above average prevalence rates when compared to the England average as detailed below:

	COPD	Asthma
NHS England average	**1.93%**	**5.93%**
North Staffs CCG	2.34%	6.38%
Stoke on Trent CCG	2.50%	6.19%
Cannock Chase CCG	2.49%	5.82%
SES & Seisdon CCG	1.84%	6.05%
Stafford & Surrounds CCG	1.70%	5.98%

Above England average
Below England average

According to the Department of Health deprived populations have the highest prevalence and the highest under-diagnosis of COPD. Stoke on Trent is one of the 20 Local Authority Districts with the highest proportion of their neighbourhoods in the most deprived 10% of neighbourhoods nationally on the Index of Multiple Deprivation 2015. Whilst Staffordshire is a relatively affluent area there are notable pockets of high deprivation in some of its urban areas with nine per cent of its population living in the most deprived fifth of areas nationally.

Taking this into account estimated to reported prevalence rates for COPD all CCGs are below expectations suggesting that a significant proportion of people are currently undiagnosed. The table below indicates the estimated prevalence rates for our local population:

CCG	Estimated Prevalence	Reported Prevalence
North Staffs	3.22%	2.34%
Stoke On Trent	4.21%	2.50%
Cannock Chase CCG	2.53%	2.49%
SES & Seisdon CCG	2.47%	1.84%
Stafford & Surrounds CCG	2.50%	1.70%

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	√
Domain 2	Enhancing quality of life for people with long-term conditions	√
Domain 3	Helping people to recover from episodes of ill-health or following injury	
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

2.2 Local defined outcomes

The service aims to achieve the following outcomes:

- Improved quality of life for patients with COPD and Asthma through increases in the number of people accurately diagnosed at an early stage
- Increase the proportion of patients with COPD and Asthma who are diagnosed comparing recorded prevalence to estimated prevalence rates.
- Drive up standards in diagnostic spirometry through the use of quality assured equipment and which is only performed by fully trained and competent staff that have been assessed in line with ARPT or equivalent standards of recognised training.

3. Scope

3.1 Aims and Objectives of Service

The overall aim is to achieve a locality-based Spirometry service which drives up clinical outcomes and quality of life for patients and their carers; services shall be strongly linked into the localities they serve and establish close working relationships with Primary Care.

The high-level objectives of the Service are:

- to increase the proportion of people with COPD / Asthma who are diagnosed comparing recorded prevalence with predicted prevalence;

- to increase the number of people accurately diagnosed at an early stage of the disease;
- to ensure the accuracy of diagnosis and severity assessment in people with COPD / Asthma;
- to help to decrease the number of people dying prematurely from COPD / Asthma;
- to ensure that users of the Service have a positive experience of care;
- to enhance the quality of life for people with COPD / Asthma;
- to ensure effective communication between relevant health professionals.

3.2 Service Description/Care Pathway

The Spirometry and Assessment Service is designed to meet the needs of patients who are deemed to be at risk and display the symptoms suggestive of COPD or Asthma, but who have not already received a diagnosis confirmed by quality-assured diagnostic spirometry.

Services shall be provided as a hub and spoke model mapped to localities. All eligible patients should be referred to the Spirometry and Assessment Service by a Clinician within General Practice as per specified referral criteria.

The Provider shall:

- Manage all referrals into the Service including assessment against eligibility criteria;
- Ensure that all patient data is transferred securely and in-line with information governance requirements;
- Provide a prescription for salbutamol for the named patient which will enable the clinician performing spirometry to administer the drug;
- Contact patients to arrange appointments for their test within five (5) working days of receipt of referral;
- Provide the patient with confirmation of their appointment, for eligible patient's appointments should take place within three (3) weeks of making initial contact with the patient. For patients currently receiving antibiotic and or oral steroids, assessments should take place within six (6) weeks.
- Provide the patient with a patient information leaflet in advance of their appointment date detailing clear instructions on inhaler advice, clinically stable, loose clothing, what the tests involve and length of time to carry out the test.
- Check that any pre-visit requirements have been adhered to by the patient before performing the test;
- Perform spirometry, reversibility testing and interpretation in accordance with the Guide to Performing Quality Assured Diagnostic Spirometry (2013);
- Electronically forward all test results and interpretation back to the referring GP to enable follow up and ongoing management within two (2) working days;
- Where the need arises, ensure mechanisms are in place for test results and interpretation to be forwarded to primary care, community services, pulmonary rehab and secondary care.

The content of the spirometry procedure should include:

- An appropriate review of patients health, including checks for potential contra-indications, that the patient is safe to undergo the test and meets the criteria;
- Recording of spirometry and reversibility test results (see section 3.2.1); tests shall

be performed by an operator trained and assessed to ARTP as identified in section 3.2.4;

- Interpretation of the results by a suitably trained and qualified health professional in line with ARTP as identified in section 3.2.4;
- Results of patients diagnosis are classified and recorded (including scanning of hard copies where generated) as mild, moderate, severe or very severe and stored as per section 3.2.3;

3.2.1 Reversibility Testing

In most patients, routine spirometric reversibility testing is not necessary as a part of the diagnostic process or to plan initial therapy with bronchodilators or corticosteroids.

However in some cases reversibility testing may need to be undertaken if the baseline spirometry reveals an obstructive picture or if asthma is suspected. In all cases Bronchodilator administration should be standardised as follows:

- Administer bronchodilator (usually 4 x 100mcg salbutamol as single puffs via spacer or 2.5mg via nebuliser)
- Perform spirometry after 15 minutes

3.2.2 Calibration

Calibration of spirometry test equipment should be performed using a 3litre syringe following the manufacturers recommended procedure.

For the device to be within calibration limits it must read +/- 3% of true. Calibration should be verified prior to every clinic / session or after every 10^{th} patient (whichever comes first).

A Calibration log shall be maintained by the Provider; this shall include a log of all problems and document all repairs / software updates related to each specific spirometer.

Any necessary cleaning and maintenance processes should be carried out on a regular basis according to the manufacturer's instructions with reference to local guidelines / protocols.

3.2.3 Storing & Communicating Results

Providers procedures for data storage should ensure:

- Secure digital backup of the tests; results and traces should be stored electronically in such a way that the data cannot be easily lost/corrupted or altered.
- Heat sensitive paper traces are photocopied or scanned as they can fade with time or changes in temperature;
- Good quality, clearly presented reports with the minimum amount of patient data to comply with information governance procedures;
- Ease of access and facility to share results between primary care, community services, pulmonary rehab and secondary care.

3.2.4 Training / Workforce / Staffing

Health care professionals who perform spirometry will have completed an approved competency-based training course in spirometry and will be expected to keep their skills up to date. Key to quality assured diagnostic spirometry is the establishment of a national register of certified healthcare professionals and operators.

The Provider shall ensure that all staff either performing and/or interpreting spirometry tests are competent and hold a certificate with the Association for Respiratory Technology and Physiology [ARTP]; individuals shall be listed on the national register according to the category of certification they have achieved.

Levels of certification include:

- Foundation (performing only)
- Interpretation
- Full (Foundation and interpretation)
- Paediatrics

3.3 Population Covered

The Provider shall provide services to all Service Users, residing in an area covered by the Staffordshire or Stoke on Trent CCGs for whom the Commissioner is responsible for funding healthcare services.

3.4 Any Acceptance and Exclusion Criteria and Thresholds

Acceptance Criteria

- Registered with a GP in either the Staffordshire or Stoke on Trent CCG areas
- Aged 16yrs+ for COPD Diagnosis
- Aged 5yrs+ for Asthma Diagnosis

- For suspected COPD – any of the following indicators must be present in an individual aged 35yrs+:
  - Dyspnoea that is:
    - Progressive
    - Characteristically worse with exercise
    - Persistent
  - Recurrent wheeze
  - Chronic cough (may be intermittent, and/or unproductive)
  - Chronic sputum production
  - History of exposure to risk factors and host factors:
    - tobacco smoke/smoke from cooking and heating fuels, occupational dusts and chemicals
    - family history of COPD and/or childhood factors
  - Recurrent lower respiratory tract infections
  - Frequent winter 'bronchitis'

- Asthma Patients - displaying the following clinical features:
  - Chronic unproductive cough
  - Significantly variable breathlessness
  - Night-time wakening with breathlessness and/or wheeze
  - Significant diurnal or day-to-day variability of symptoms

- Emphysema - suspected or CT proven
- Breathlessness with suspected lung disease
- Bronchiectasis
- Clinically suspected restrictive lung disease
- *Monitoring of lung function where there is clinical concern for alternative or additional diagnosis to account for patient's deterioration.*

Exclusion Criteria

- Not seen by GP or Practice Nurse;
- Aortic aneurysm, pregnancy;
- Existing or suspected respiratory infection;
- Haemoptysis of unknown origin;
- Pneumothorax;
- Unstable cardiovascular status; recent (within 1 month) myocardial infarction, uncontrolled hypertension, pulmonary embolism or chest pain;
- Uncontrolled hypertension or history of haemorrhagic cerebrovascular event;

3.5 Interdependence with other services/providers

- General Practitioners
- Midlands Partnership Foundation Trust Respiratory Team
- University Hospital of North Midlands
- University Hospitals of Derby and Burton NHS Foundation Trust
- Royal Wolverhampton Trust
- Heart of England Foundation Trust
- Home Oxygen Services
- Walsall NHS Trust

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

- NICE Clinical Guideline CG101 – Chronic Obstructive Pulmonary Disease Diagnosis & Management June 2010
- NICE Quality Standard 10 for COPD February 2016
- NICE Clinical Guideline NG80 - Asthma: diagnosis, monitoring and chronic asthma management November 2017

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

- A Guide to Performing Quality Assured Diagnostic Spirometry 2013

4.3 Applicable local standards

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4 Parts [A-D])

5.2 Applicable CQUIN goals (See Schedule 4 Part [E])

CQUIN payments will not be applicable to this contract

6. Location of Provider Premises

The Provider's Premises are located at:

The Provider shall ensure that the Services are provided taking into account patient need and choice mapped to the CCG Localities. Providers are to ensure that venues are easily accessible to patients, including availability of public transport and car parking.

7. Individual Service User Placement

Not Applicable.

SCHEDULE 4 – QUALITY REQUIREMENTS

A. Local Quality Requirements

Exceptions will be considered for all LQRs.

	Quality Requirement	Threshold	Method of Measurement	Consequence of breach	Timing of application of consequence
1	Following receipt of referral all patients are contacted within five (5) working days to arrange an appointment	100%	As a % of all referrals received Monthly activity report	GC9	Monthly
2	Referral to diagnostic investigation is completed within three (3) weeks following receipt of referral for eligible patients / six (6) weeks for those on antibiotic or oral steroids.	95%	As a % of all diagnostic investigations completed Monthly Activity Report	GC9	Monthly
3	Referring clinician to receive an electronic copy of test results and interpretation report within 2 working days.	90%	As a % of all reports issued Monthly Activity Report	GC9	Monthly
4	Evidence of calibration prior to every clinic / session or after every 10th patient (whichever comes first).	100%	Quarterly audit of calibration log	GC9	Quarterly
5	Staff members have completed an approved competency-based training course in spirometry and are registered on a national register of certified healthcare professionals and operators.	100%	Annual audit	GC9	Annual
6	GPs referring to the service shall be satisfied / very satisfied with the service	90%	GP Survey Report submitted to Commissioners	GC9	6 monthly audit
7	Patients completing the survey shall be either satisfied or very satisfied with the service	90%	Review of Service Quality Performance Reports As a % of surveys completes	GC9	6 monthly audit

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

A. Reporting Requirements

Local Requirements Reported Locally				
Data set of all services delivered by the provider split by CCG in the immediate preceding month to include; • Total number of referrals (new diagnosis / monitoring) • Total number of appointments • Referral to diagnostic investigation completed within: (percentage & number) ➢ 0-3 weeks ➢ 4-6 weeks ➢ 7-9 weeks ➢ 10 weeks + • Outcome of consultation: (percentage & number) ➢ Normal ➢ Obstructive defect with no reversibility ➢ Obstructive defect with reversibility • Time elapsed since completion of diagnostics and reporting back to patients registered GP: (percentage and number) ➢ 0 - 2 days ➢ 3 - 5 days • Number of patients completing a customer satisfaction survey	Monthly	Excel workbook	Submit Validated data to Coordinating Commissioner Within 15 Operational Days of the month to which it relates	