SCHEDULE 2 – THE SERVICES

A. Service Specifications

NOUS SPECIFICATION

Service Specification No.	
Service	Diagnostic Services – Direct Access Non-Obstetric Ultrasound Service
Commissioner Lead	Greater Huddersfield CCG
Provider Lead	
Period	
Date of Review	

1. Population Needs

The NHS supports the need to develop improved access to diagnostic tests as part of the drive to reduce waiting times and improve choice options for Patients. The need to develop community based diagnostic services is supported by the Royal College of Radiologists and Royal College of General Practitioners as part of a service strategy to improve access to tests and ensure these tests are delivered at the right stage of the Patient care pathway. The overarching aims of the service are:

- To ensure Patients receive the right test at the right time and in the most clinically appropriate local setting;
- To ensure diagnostic testing is integrated across pathways of care, that the report and images follows the Patient and that there is no unnecessary duplication of investigation;
- To enable Patients and referring clinicians to access a choice of provision according to Patient choice, clinical need and relevant care pathway; and
- To ensure diagnostic tests are appropriate, necessary, clinically correct, of high quality, with timely access and reporting.
- To develop local service provision as part of a diagnostic commissioning plan which aims to improve access and choice for Patients.

2. Scope

2.1 Aims and objectives of service

A local, direct access non-obstetric ultrasound service with staff qualified to appropriate levels of skill and experience, using ultrasound equipment which complies with the guidance set by the Royal College of Radiologists, connection to NHS image transfer solutions, the ability to integrate with the Choose and Book system, robust performance management systems and stringent levels of clinical governance.

The care pathway being commissioned is pre-appointment communication with Patients, the diagnostic investigation and a report being sent to the referrer, which covers not only the description of the investigation and the findings, but also where appropriate covers any recommendations for further imaging or investigation and advice on management. Structured reporting will be encouraged to support local referrers in their options for further clinical management. The service will need to be fully quality assured,

validated and supported by the local Commissioners.

The Provider must aim to provide an excellent Patient experience during all parts of the process – to include the examination and the administrative services. In order to measure this, Providers should have in place robust mechanisms for collecting Patient feedback using approaches that reflect the diverse nature of their Patient population. This should include as a minimum, a Patient satisfaction survey, and one real time feedback mechanism. There must be a sound process for receiving and dealing with suggestions, compliments and complaints.

The aim of the service is to aid early diagnostics and avoid the need for unnecessary referral to secondary care, or to support the shift of activity in to a primary care setting, where this will improve access. Where there are clear secondary care clinical pathways with ultrasound as a core component, it is more appropriate for this diagnostic to be undertaken as an integral part of the clinical pathway.

2.2 Service description/ care pathway

2.2.1 Referral

- Referral should ideally be via the Choose and Book system. As a minimum referrals should be sent by secure email. Providers would be expected to aim to be connected to the Choose and Book system (directly or indirectly bookable) at the earliest opportunity.
- It is anticipated that the majority of referrals will be direct from General Practitioners or a Clinical Assessment Service. Some referrals may be received from secondary care following specific agreement with local Commissioners.
- Providers must provide literature for GPs and referrers to assist them in the decision making processes associated with the most suitable type of diagnostic test for the Patient and presentation that will achieve the best and quickest diagnostic outcome;
- Patients should be contacted within a maximum of [5] working days of acceptance of the referral;
- The Patient should be offered a choice of day and time of appointment that is convenient to them;
- The Provider should ensure Patients have an adequate understanding of the proposed ultrasound scan before the appointment and any particular preparations that they will need to make, by providing written information in advance that explains the purpose of the ultrasound scan, what it involves and when and how they can expect to receive the results. This information should be reinforced on arrival at the appointment, consistent with the written information already received;
- The Provider shall not discriminate between or against Patients or Carers on the grounds of gender, age, ethnicity, disability, religion, sexual orientation or any other non-medical characteristics. The Provider shall, at its own cost, provide appropriate assistance and make reasonable adjustments for Patients and Carers who do not speak, read or write English or who have communication difficulties; and
- Providers will provide to Commissioners detailed referral statistical information on referrers, referring organisation, service utilisation, referral rejection rate and clinical outcome to allow refinement of the clinical pathway.

2.2.2 Assessment

- The Provider will provide triage of referrals to meet referral criteria and provide information within 1 working day where a referral does not meet the established criteria for examination;
- Scanning should be undertaken within [10] working days of acceptance of referral and at an absolute maximum of [20] working days ([4] weeks);
- A minimum of verbal consent should be obtained for all Patients and should be recorded in the ultrasound report;
- Patients must be offered the option of chaperone provision for the examination. The definition of intimate or invasive ultrasound may differ between individual Patients for ethnic, religious or cultural reasons and should be considered by the clinician;
- The Provider should be aware of the weight limit for various examination couches and ensure that the appropriate equipment is available or make suitable alternative arrangements when necessary; and
- The Provider will not usually provide the result of the diagnostic test at the time of the investigation, but will explain that a report will be sent without delay to the referrer. However, where the patient requests further information the operator will use their knowledge and discretion to determine the

appropriateness of imparting the result within their scope of practice.

2.2.3 Report

- A written clinical report should be sent to the referrer (and GP if this is not the same individual) within [2] working days following the examination and maximum of [5] working days. The information should be communicated electronically via a secure network.
- The Provider shall ensure that the Diagnostic Report is produced according to the guidance set out within the document 'Standards for the Reporting and Interpretation of Imaging Investigations' as published by the Royal College of Radiologists and as updated from time to time in the form agreed with the Authority, as a minimum;
- The report will provide the referrer with a differential diagnosis wherever possible – this will be based upon the presenting complaint described in the referral and the objective findings of the scan;
- If the sonographer requires input from a Consultant Radiologist, this should be available within 24 hours of the investigation;
- Patients with a suspected cancer are specifically excluded from this service. However, there will be occasions when a diagnostic study identifies a serious and/or unexpected pathology. The Provider will need to have a clear Patient pathway for this group of Patients, which will ensure that the referrer is made aware of the potential diagnosis and the report is expedited for onward communication and that the diagnostic images are immediately available for review within the secondary care institution. This would include an immediate telephone conversation with the referrer, in line with guidance set out within the document 'Standards for the communication of critical, urgent and unexpected significant radiological findings', RCR;
- GPs or other clinical staff wishing to discuss individual cases will be provided access to the reporting individual through a central contact number;
- The Provider shall submit detailed protocols governing sonographer performance of ultrasound procedures;
- Evidence that these have been developed in concert with a radiologist expert in ultrasound shall be provided and that there is a programme of constant review of the examination protocols;
- A clearly defined pathway for the images to be reviewed by a radiologist in concert with the sonographer where there is uncertainly about the findings or for example when further imaging investigations are required;
- The image and report is stored in electronic format, in accordance with The Royal college of Radiologist 'Retention and Storage of Images and Radiological Patient Data' publication ideally via a Picture Archiving and Communications System (PACS) system; and
- The image and report is forwarded, at no charge, to other Providers of NHS funded treatment applicable to the Patient care pathway, within a maximum of a 5 working days of the request and sooner if necessary to correspond with patient care needs. This will require connection to the National Image Exchange Portal (IEP).
- Reasonable repeat requests for images and reports will be made available at no extra charge while the Provider holds a relevant contract.

a. Population covered

The population to be covered is the current populations of Greater Huddersfield and Calderdale geographical areas.

Services are to be provided within each of the following CCG areas. Providers may be an AQP for one or more of these areas; requirements apply to each of the areas for which they wish to be an AQP and patients from the entire population will be able to access any service provision within any of the geographical areas. Providers will be expected to work with commissioners to optimise access to the services within each geographical area.

Geographical area covered by Calderdale Clinical Commissioning Group,
Geographical area covered by Greater Huddersfield Clinical Commissioning Group,.

2.4 Acceptance Criteria

Referrals for inclusion:

- General abdominal – includes assessment of the aorta, biliary tract, gallbladder, inferior vena cava,

kidneys, liver, pancreas, retroperitoneum and spleen;
- Gynaecology – including transabdominal and transvaginal;
- Renal / bladder / prostate;
- Scrotal / testicular;
- Musculoskeletal; and
- Vascular – includes suspected DVT.

The Provider will comply with relevant commissioner policies on clinical referral thresholds and procedures of limited clinical value.

The referring clinicians should consider the appropriateness of the referral based upon the integral nature of the diagnostic and the clinical pathway, in their deliberations with the Patient, in their choice of Provider.

The Provider must offer assurance that the Professional performing the examination has sufficient module based training to undertake the particular scan. It is acknowledged that much of the practical and academic training of sonographers is module based. It is critical that the training and experience of the sonographer is relevant to the nature of the examination being performed.

2.4.2 Exclusion Criteria

Clinical exclusions

Cancer – any Patient with suspected cancer should be referred through the two week wait referral pathway;

Ultrasound guided procedures;

Obstetric care;

Scans for:

- Breast;
- Cardiac Imaging;
- Chest;
- Ophthalmology;
- Superficial masses or lumps in the neck, axilla or groin; and
- Thyroid.

Other exclusions

Children under the age of 18; and

Non-NHS Patients;

2.5 Interdependencies with other services

The Provider needs to develop their relationships with other Providers to become an integral member of the Health and Social Care Community. This includes third sector organisations providing help and support for Patients. The development of local clinical networks will be encouraged with the aim of providing parallel services which provide complementary services allowing for further clinical services to be offered closer to home and within the community. The role of service users as key stakeholders will be an important component of this development and Providers should ensure effective mechanisms for their involvement and develop a positive relationship with the local involvement network (Healthwatch).

The Provider may need to develop relationships within the Health Community to enable fulfilment of the Quality Assurance requirements.

The Provider will be required to be involved in local care pathway work and discussions, ensuring the best and most efficient means of treating patients are adopted, including the movement of the relevant clinical information (i.e. images and clinical output report).

3. Applicable Service Standards

3.1 Applicable National Standards

- Ultrasound Equipment Evaluation Project (UEEP) recommendations as published from time to time – MHRA.
- Right Test, Right Time, Right Place - Royal College of Radiologists and Royal College of General Practitioners (2006).
- Making the Best Use of a Department of Radiology, 6th edition (MBUR6) - Royal College of Radiologists (2007).
- Standards for Ultrasound Equipment - Royal College of Radiologists (2005).
- Ultrasound Training, Employment and Registration – Society and College of Radiographers (2010).
- Guidelines for Professional Working Standards: Ultrasound Practice – United Kingdom Association of Sonographers (2008). UKAS merged with the SCoR on 01/01/2009.
- Standards for the communication of critical, urgent and unexpected significant radiological findings - Royal College of Radiologists (2008).
- Society and College of Radiographers suggested documents:
  http://doc-lib.sor.org/scope-practice-medical-ultrasound
  http://doc-lib.sor.org/ultrasound-training-employment-and-registration
  http://doc-lib.sor.org/profession-standards-independent-practitioners
  http://doc-lib.sor.org/guidelines-profession-working-standards-ultrasound-practice
- Industry Standards for the Prevention of Work Related Musculoskeletal Disorders in Sonography – Society of Radiographers (2006).
- Prevention of Work Related Musculoskeletal Disorders in Sonography - Society of Radiographers (2007).

This is intended as a non-exhaustive list. Clause [16] takes precedence.

3.2 Applicable Local Standards

3.2.1 Staffing

The Provider shall ensure that the service is delivered by Staff who meet the following service requirements:

- UK Registered Radiologists on the GMC Specialist Register who have:
- Performed and reported on a minimum of 900 ultrasound scans in the last 12 months; and Sonographers who:
- have performed and reported on a minimum of 900 ultrasound scans in the last 12 months; and
- meet the relevant specification set out in the 'National Occupational Standards for Imaging' for the anatomical area to be scanned (https://tools.skillsforhealth.org.uk/competence/);
- have successfully completed an appropriate postgraduate certificate or diploma in medical ultrasound approved and validated by a Higher Educational Institution and accredited by the Consortium for the Accreditation of Sonographic Education (CASE); or
- the Certificate / Diploma of the College of Radiographers in Medical Ultrasound, or hold an equivalent level of qualification in medical ultrasound (for example if trained overseas) or individual accreditation from the Society for Vascular Technology for vascular imaging; and
- have maintained their Continuing Professional Development in accordance with professional guidelines.
- It is suggested that all sonographers who are not otherwise statutorily registered are registered on the Public Voluntary Register of Sonographers, which is administered by the College of Radiographers. (Please note: Acceptance on to the Voluntary Register does not in itself authenticate competence or fitness to practice).
- Sonographers who are suspended or removed from statutory registration will not be allowed to continue with clinical practice in this service.
- Staff will have English as a first language or have passed a suitable English language examination to the level of requirement set out on the Health Professions Council website

(http://www.hpc-uk.org/apply/international/requirements/).

3.2.2 Equipment

The Provider shall provide equipment that meets or exceeds the following:

- Complies with the latest guidance from the National Imaging Clinical Advisory Group and Professional Bodies;
- Transducers that ensure good visualisation at sufficient depth of image without significant loss of accurate spatial resolution; and
- Be capable of flow imaging and measurement.
- Electrical Safety Testing is required annually with regular maintenance and quality assurance testing;
- Details of maintenance contracts to include regular and emergency service cover must be provided; and
- Replacement schedule must be available with the maximum age of equipment of 7 years.

3.2.3 IM&T

Where data is transferred from the Ultrasound Scanner to the provider, PACS or image store the removable media device must have encryption software. Standard operating procedures for handing the data will be implemented as required by the commissioner.

Provision of Digital Data between the Provider PACS systems should be through the Image Exchange Portal or other data sharing systems to other providers as specified by the commissioner, or in clinical circumstances that require the transfer of the image to support the safe treatment of the patient.

In the event of cancellation of the contract (for whatever reasons), the Provider will be required to maintain systems to allow continued access, in a timely manner, to all of the patient information, images and associated patient records.

3.2.4 Facilities

Whilst it is anticipated that the service will be provided from a number of locations. Each site must meet the minimum requirements of:

- A room, which is at least 12 sqm and supports wheelchair access;
- Includes a hand washbasin and adjustable lighting;
- Is supported by a staffed reception area and waiting area; and
- Has access to toilet facilities, which include disabled access.

It is desirable that the room has an air conditioning system.

Musculoskeletal disorders are the most common work-related illness in Britain and represent a significant potential risk. There are guidance documents, which focus upon preventing, and controlling musculoskeletal disorders for radiographers, other health care professionals engaged in sonography, and Providers must be aware of and abide by this advice.

3.2.4 Quality Assurance

Ultrasound services are very operator dependent. It is therefore necessary for a clear and stringent quality assurance process to be an integral requirement of the service, at individual operator level. Whilst independent practice is appropriate for sonographers, working in isolation is not and this must be addressed by Providers.

The proposed Quality Assurance process must include, as a minimum:

Ongoing 5% blind audit of image and report review for each sonographer, radiologist or other clinician – exact mechanism to be agreed with Commissioner;

Clear definition of the audit process and the trigger values for detailed review of performance;

An annual observed competency assessment as part of an annual appraisal relevant to the area of practice;

Clear process of education/remediation in the event of significant error or persistent poor performance; and

Participation by sonographers and all other clinical staff in 'local errors meetings' or similar clinical governance process and information on these meetings and subsequent actions to be shared with the commissioner; and

Providers should aim to offer sonographers the opportunity of rotation through an acute clinical service setting (potentially that of an alternative Provider) for a minimum of 3 weeks every two years.

The Provider must follow The British Medical Ultrasound Society (BMUS) safety guidelines and demonstrate understanding of the 'As Low As Reasonably Achievable' (ALARA)1 principle, and have an effective system in place to ensure awareness of recent safety publications by national and international bodies.

4. Key Service Outcomes

Key Service Outcome	**Method of Measurement**
Patients reporting a good level of satisfaction of the service.	Patient Satisfaction Survey to be sent out to a minimum of 95% of Patients using the service, with a minimum response rate target of 30%. Target of 95% of Patients reporting good level of overall satisfaction.
Reduced referral to secondary care and improved conversion rate – as proxy for increased appropriateness of referrals.	Secondary Users Service (SUS) system – using previous year as baseline.
Image and Report to follow Patient pathway – no repeat scanning without clinical rationale.	Commissioner to audit random sample – results to be extrapolated.
Improved targeting of referrals to right secondary care clinic first time – fewer Consultant to Consultant referrals	SUS system – using previous year as baseline.

5. Location of Provider Premises

The Provider will carry out the service at the following premises:

6 Prices and Payment

Prices are based on national currency applicable in the year the activity takes place (for the purpose of the period 1 April 2015 to 31 March 2016 this will be the Enhanced Tariff Option).

HRG Code	Description	Price (exclusive of MFF)
RA23Z	Ultrasound, scan 0 – 20 mins	Current PbR tariff - £43
RA24Zb	Ultrasound, scan 20 – 40 mins	Current PbR tariff - £55

There will be no payment made for appointments where patients do not attend.

The commissioners expect the majority of procedures to be charged at the national tariff RA23Z. It is accepted that there is significant variation in local coding practice for these procedures, but there will need to be compelling evidence provided to the Commissioner for any 3 month period in which more than 50% of activity is charged at RA24Zb. In the medium term Commissioners expect that at least 90% of activity will be at code RA23Z.