Service Specification No.	NCL GPDADI / CCCG UCLH MSK MRI 003
Service Specification Title:	Service Specification for: a) North Central London (NCL) Clinical Commissioning Groups (CCGs) GP Direct Access Diagnostic Imaging Service, and b) University College London Hospitals NHS Foundation Trust (UCLH)/Camden CCG Musculoskeletal (MSK) Magnetic Resonance Imaging (MRI) Service
Services	Direct Access Diagnostics Imaging Service modalities covered; • Non-Obstetric Ultrasound • MRI • X-ray • Cardiology Diagnostic Services (Ambulatory ECG, Ambulatory Blood Pressure Monitoring, ECG and Echo) • Dual Energy X-ray Absorptiometry (DEXA) Scanning (Please refer to Appendix F to list of modalities by Commissioner)
Commissioner Leads & Associates	For NCL CCGs GP Direct Access Diagnostic Imaging Service: • Host Lead Commissioner: NHS Camden CCG • Associates: NHS Barnet CCG, NHS Enfield CCG, NHS Haringey CCG, NHS Islington CCG For Camden CCG/ULCH MSK MRI Service: • Host/Lead Commissioner: ULCH
Provider Lead	TBC
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Version	**Date**	**Author**	**Comments**
000	2014.04.14	Ian Ross	Specification used for previous contract award
001	2019.02.15	Andrew Wilsher-Gawthorpe	Initial redraft reflecting clinical feedback
002	2019.03.08	Andrew Wilsher-Gawthorpe	Amendments following Clinical Workshop 7th March 2019
003	2019.05.01	Andrew Wilsher-Gawthorpe	Removal of MRI Pelvis & Abdomen (Liver, Adrenals)

CONTENTS

1. POPULATION NEEDS

1.1 National Context

1.1.1 The London NHS Diagnostic Service offers GPs and other healthcare professional's direct access to high quality diagnostic and imaging scans and tests throughout London, including MRI, Ultrasound, Cardiac, DEXA and X-Ray.

1.1.2 The NHS supports the need to develop improved access to diagnostic tests as part of the drive to reduce waiting times, improve choice options for patients as well as early diagnosis to improve outcomes. The need to develop and improve access to community based diagnostic services is supported by the Royal College of Radiologists and Royal College of General Practitioners.

1.1.3 To develop local service provision as part of a diagnostic commissioning plan which aims to improve access and choice for Patients.

1.2 Local Health Needs

1.2.1 The population of the five CCGs is approximately 1.44 million with 237 GP practices[1].

1.2.2 The North Central London cluster of CCGs (Barnet, Camden, Enfield, Haringey and Islington) have highlighted some important areas for consideration:

1.2.2.1 The Commissioners require direct access diagnostic services with staff qualified to appropriate levels of skill and experience, using equipment which complies with the guidance set by the Royal College of Radiologists, has connection to NHS image transfer solutions, has the ability to accept over a secure connection and to share securely results and reports electronically. They must have the ability to integrate with the E-Referral System, where applicable at a local level, robust performance management systems and stringent levels of clinical governance. The Provider(s) will be expected to comply with local pathways and protocols to ensure digital interoperability, delivery of integrated personal health records and the use of electronic referral and image transfer solutions.

1.2.2.2 The Provider(s) would be expected to provide transport where this is necessary to ensure access for all patients. The services should be provided locally and there may be some variation in requirements between CCGs which will be identified in service specifications. The Provider will provide transport where required for patients with disabilities and/or mobilisation difficulties. Those requiring transport will be usually determined by the GP in advance and indicated as part of the referral. Ambulance and escort services are excluded as per clause 3.4.2.1. Transport will be billed monthly

[1] NCL STP Case for Change September 2016

to the respective CCG with the description 'GP Direct Access Diagnostic Imaging Service - Patient Transport'.

1.2.2.3 For non-urgent referrals patients must have access to diagnostics within no more than 15 days locally, or in agreement with individual CCGs at a local level if clinics are held less frequently.

1.2.2.4 For urgent referrals patients must have access to diagnostics within no more than 5 days locally, or in agreement with individual CCGs at a local level if clinics are held less frequently.

1.2.2.5 Provision for MRI, Ultrasound, Cardiac, DEXA and X-Ray services should be available in each of the 5 boroughs or within 1 mile of the neighbouring NCL borough(s) boundary (see Section 9).

1.2.2.6 Providers must be able to electronically receive requests, transfer and receive results and data over a NHS N3 compliant secure connection or equivalent, whilst keeping up to date with local systems and process developments.

1.2.2.7 The successful provider will be expected to work with the NCL STP and CCGs to implement new pathways of care as these are developed and work with commissioners to implement of pathways which may lead to the reduction of imaging activity direct from GPs, which are felt to be clinically unnecessary. This may be linked to the development of new referral criteria (through the diagnostics work) or new MSK / Orthopaedic / Neuro pathways of care such as the introduction of MSK Single Point of Access or First Contact practitioner.

2. OUTCOMES

2.1 This service will:

- Improve the quality of life for low risk patients by providing rapid access to diagnostics in a setting closer to home
- Increase choice for patients by offering community based services at times and venues that suit patient needs
- Facilitate referrers to be able to manage patients safely and effectively within the primary care setting
- Reduce unplanned hospital admissions and waiting times for services within secondary care and reduce hospital outpatient appointments and follow-ups.
- Develop and deliver innovative services, which are also cost effective
- Develop Integrated care pathways across the health and social care system to achieve holistic care
- Improve the quality of GP referral and management of cardiology within primary care

2.2 Key service outcomes are outlined in Table A.

Table A: Key Service Outcome

Key Service Outcome	Method of Measurement
Patients reporting a good level of satisfaction of the service.	Patient Satisfaction Survey to be sent to a minimum of 90% of Patients using the service, with a minimum response

	rate target of 30%. Target of 75% of Patients reporting good level of overall satisfaction.
Reduced referral to secondary care and improved conversion rate – as proxy for increase appropriateness of referrals. Only referrals for patients meeting referral thresholds are accepted by the service	1. Secondary Uses Service (SUS) system – using previous year as baseline. 2. Audit of feedback reports to referrers to measure • Appropriateness of referral • Clarity of management plan and instructions to referrer
Report and images to follow patient pathway electronically (via agreed image exchange portal(s)) – 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.

3. SCOPE

In complying with this section, the Providers attention is also drawn to Information Management Technology (IMT) requirements outlined in clause 4.16.

3.1 Aims and Objectives of Service

3.1.1 A local, direct access service with staff qualified to appropriate levels of skill and experience, using relevant equipment which complies with national guidance including the Royal College of Radiologists, connection to NHS image transfer solutions, the ability to integrate with the E-Referral System, robust performance management systems and stringent levels of clinical governance.

3.1.2 The care pathway being commissioned includes the pre-appointment communication with Patients, the diagnostic investigation and a report being sent to the referrer and an image, which covers not only addresses the question ask, 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 should 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.

3.1.3 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 robust process for receiving and dealing with suggestions, compliments and complaints. Refer to patient experience for more detail.

3.1.4 The aim of the service is to aid early diagnostics and therefore diagnosis and avoid the need for unnecessary referral to secondary care clinicians for

conditions that can be appropriately managed in Primary Care or to support the shift of activity in to a primary care setting, where this will improve access. Where it is clear secondary care clinical pathways need to be used and it is important to ensure the diagnostic test results, reports and images are available to secondary care in a standardised format (consistent with secondary care reporting requirements.

3.1.5 It is important that there are evidence based guidelines for accepting the referral; as an example, if a GP referral for an MRI is not appropriate, the Provider must not accept that referral and inform the referrer of the most appropriate diagnostic. Where available and requested, the Provider should incorporate NCL guidance within referral forms.

3.2 Service Description / Care Pathway

3.2.1 Referral

3.2.1.1 As a minimum the NCL CCGs would expect a provider to have access to, be compatible with and be able to accept referrals for all modalities via the e-Referral System. However it is acknowledged that at a local level some referrals may be sent via secure NHS.net email (using established referral templates) and/or other local means as required from time to time.

3.2.1.2 Before conducting the examination, the practitioners will have access to any previous imaging and reports where the Provider has conducted the prior imaging (e.g. where a repeat may be recommended after a period of time, perhaps in relation to a cyst) or where the referrer has provided the Provider with details of a prior scan for comparison. It is noted that in the future the Commissioners hope that sharing will be possible although there is a recognition that this will have to be negotiated. Where the referrer advises then every effort should be made to ensure that a further diagnostic is appropriate both clinically and from a safety point of view.

3.2.1.3 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 and other services where this is agreed by commissioners. It is noted that the majority of referrals are from GPs, and it is agreed that the referral routes already in place at the time of commencement of the contract which come under clinical assessment service, are all still valid.

3.2.1.4 The Provider will upon request of the Commissioner make available literature for GPs and other referrers to assist them in the decision making processes to choose the most suitable type of diagnostic test for the Patient and presentation that will achieve the best and quickest diagnostic outcome. As part of this process of building relationships and educating about referrals, the Provider shall contribute to an annual education event for GPs about the appropriate use of different imaging modalities upon the request of the Commissioner.

3.2.1.5 Patients should be contacted within a maximum of [2] days of acceptance of the referral.

3.2.1.6 The Patient should be offered a choice on day, time and location of the appointment that is convenient to them, though a telephone and/or secure electronic booking system; if they don't accept the initial appointment then they should be offered an alternative time and date.

3.2.1.7 The Provider should ensure Patients have an adequate understanding of the proposed procedure before the appointment and any particular preparations that they will need to make, by providing written information in advance that explains the purpose of their visit, what it involves and when and how they can expect to receive the results in a language that they can understand. This information should be reinforced on arrival at the appointment, consistent with the written information already received.

3.2.1.8 The Provider shall work within a framework of non-discriminatory practice, in keeping with the Equalities Act 2010. All patient facing staff should receive mandatory equality and diversity training. The Provider shall provide appropriate assistance and make reasonable adjustments for Patients and Carers who do not speak, read or write English or who have communication difficulties, in keeping with the Accessible Information Standard (See www.england.nhs.uk/ourwork/accessibleinfo).

3.2.1.9 Providers will provide to Commissioners detailed referral statistical information on referrers, referring organisation, service utilisation, referral rejection rate and diagnostic outcome to allow refinement of the clinical pathway.

3.2.2 Assessment

3.2.2.1 The Provider will provide triage of referrals to meet referral criteria and provide information (to the referee) within 1 working day where a referral does not meet the established criteria for examination with a recommendation on the correct diagnostic required.

3.2.2.2 Diagnostics should be undertaken within 15 days (for non-urgent referrals) or 5 days (for urgent referrals) of referral date, at a location agreed with the patient.

3.2.2.3 A minimum of verbal consent should be obtained for all Patients and should be recorded.

3.2.2.4 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.

3.2.2.5 The referrer shall ensure that that patient's weight is recorded on the referral. 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.

3.2.2.6 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.

3.2.3 Report

3.2.3.1 A written clinical report should be sent to the referrer within [3] days following the examination along with the scan images. This information should be communicated electronically via a secure network (see 4.6 IMT) and must address the question asked by the referee.

3.2.3.2 The required report format is presented in Appendix G. 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;
- A response to the clinical questions that have been asked
- A comprehensive management programme
- Author details (name, contact details, General Medical Council number)

3.2.3.3 Patients with a suspected cancer diagnosis should be requested as urgent (5 days). 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'.

3.2.3.4 GPs or other clinical staff wishing to discuss individual cases will be provided access to the reporting individual (or other suitably qualified individual e.g. radiographer or radiologist who has access to original images and report and is able to support supplementary clinical questions) through a central contact number which should operate Monday to Friday 08:00 to 20:00, and a clinician should respond where needed within 2 working hours if clinically urgent and by the next business day if non-urgent; this will be to offer the opportunity to identify the most appropriate examination and discuss the clinical findings if required. The Provider should be working towards a 7 day per week service as per local NHS ambitions. GPs or other clinical staff should also have access to the reporting individual via email.

3.2.3.5 There must be a clearly defined pathway for ultrasound images to be reviewed within 24 hours by an radiologist in concert with the sonographer where there is uncertainty about the findings or for example when further imaging maybe required;

3.2.3.6 The ultrasound team must be comprising of a network radiologists, registered ultrasonographers and, who must work together to deliver a high standard of clinical care.

3.2.3.7 The clinical team must be supported by an experienced administration team that ensures the service is patient focused, efficiently delivered with minimal patient DNA's (Did Not Attend) as well as robust GP communication to deliver excellent service to patients. There should be a text reminder facility for appointments.

3.2.3.8 The service should include

- General Abdominal to include Liver, Gall Bladder, Pancreas, Spleen, Kidneys, aorta & IVC
- Renal tract to include Kidneys, Ureters, Bladder & Prostate
- Pelvic to include Uterus, Ovaries & Adnexae
- Deep Vein Thrombosis (DVT) where local acute pathway exists
- Scrotum to include Testes and Scrotum.
- Salivary glands and thyroid
- Soft tissue lumps

3.2.3.11 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

3.2.3.12 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 2 days of the request (made by the GP, referrer or clinician) and sooner if necessary to correspond with patient care needs. This should include availability for local multi-disciplinary team meetings in line with the receiving provider image transfer and distribution protocols. This will require connection to the National Image Exchange Portal (IEP).

3.3 Population Covered

3.3.1 Qualifying patients for this service must be registered with a GP in Barnet, Camden, Enfield, Haringey or Islington and be aged of 18 years or over for all modalities.

3.4 Any acceptance and exclusion criteria

3.4.1 Acceptance Criteria

3.4.1.1 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 and the Provider should only accept referrals that meet the clinical threshold.

3.4.1.2 The Provider should have access to an open MRI facility to treat claustrophobic patients, at no additional costs to commissioners.

3.4.2 Exclusion Criteria

- Referrals received with no NHS numbers:-
  - A check will be made with the details provided to ascertain if the patient has been issued with an NHS
  - GPs will be advised to obtain a valid NHS number from CCG. A referral will be held pending confirmation of NHS number
  - No NHS number can be issued or obtained. The referral will be rejected
- Patients not registered with a NCL GP
- Patients with mobility issues that may require additional support and or equipment to undertake the diagnostics
- Abusive, violent, or threatening NHS Patients without security escort;
- NHS Patients barred from NHS services;

3.4.3 Clinical exclusions

- NHS Patients requiring general anaesthetic;
- NHS Patients who have a medical contraindication to the Activity;
- NHS Patients who are medically unfit to undergo the Diagnostic Investigation;
- NHS Patients who are medically unfit to undergo transfer to the facility e.g. non-ambulant, require continuous use of specialist medical equipment
- NHS Patient who require an image guided biopsy.

3.5 Interdependence with other services/providers

3.5.1 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).

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

3.5.3 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)

4. SERVICE DELIVERY REQUIREMENTS

In complying with this section, the Providers attention is also drawn to Information Management Technology (IMT) requirements outlined in clause 4.16.

4.1 Excluded Patients

4.1.1 The Provider shall not be required to carry out the Activity on NHS Patients who meet the exclusion criteria, section 3.4.2.

4.2 Acquisition Protocol

4.2.1 The Provider shall ensure that NHS Patients are scanned according to evidence based scanning protocols that optimise the diagnostic utility of the Investigation Output.

4.3 Report

4.3.1 The Provider will double read 2% of all examinations reported on the Provider system as part of the ongoing quality processes. These will be double read using The Provider's bespoke QA programme but scored (and reported on a monthly basis) using the discrepancy definitions. Double reads will not be charged to the Commissioner.

4.3.2 The Provider shall ensure:

- That the Diagnostic Report is produced according to the "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 format agreed with the Authority; and
- That the Diagnostic Report is always authenticated by a physician on the UK GMC specialist register, who has been Deemed Competent to report in relation to MRI and X Ray .
- The report and associated images are sent to referrer.

4.4 Good Clinical/Industry Practice

4.4.1 The Provider will be register with the Care Quality Commission (CQC), and shall make available upon Commissioner Request associated reports and action plans.

4.4.2 The Provider will deliver the service to the quality standards as defined by the Royal College of Radiologists (RCR) and as required by the Care Quality Commission (or its successor).

4.4.2 The Provider shall deliver the Services in accordance with Good Clinical Practice in respect of Diagnostic Services, Good Industry Practice in respect of Services other than Diagnostics Services and the NHS Requirements and in any event to a standard equivalent to the highest available CNST (Clinical Negligence Scheme for Trusts) General Clinical Risk Management Standard, in each case appropriate to the Service being delivered.

4.4.3 Without limitation, the Provider shall comply with the following requirements:

- Standards for Better Health;
- In a manner so as to achieve and maintain the National Minimum Standards required for Independent Clinics or if applicable Independent Hospitals under the Care Action 2014 and Health, Social Care Act 2012 and other relevant Acts of Parliament;
- IR(ME)R;
- The latest MHRA guidance/technical standards/alert notices; and
- The Royal Marsden Hospital Manual of Clinical Nursing Procedures (latest edition).

4.4.4 The Provider acknowledges that where any part of the Services is described in this document, there shall also be implied a term that in delivering that Service, irrespective of any other standard for delivery of the Service that is specified, the Provider shall at all times deliver the Services in accordance with the highest level of clinical standards that can be derived from the standards and regulations.

4.5 Facilities & Equipment

4.5.1 The Provider shall:

- Provide medical and surgical equipment, medical supplies including medicines, drugs, instruments, appliances, and materials necessary for NHS Patient care which shall be adequate, functional and effective;
- Ensure that all medical equipment complies with MHRA standards;

- Ensure that NHS Patients have adequate privacy and changing facilities that preserve their dignity.

4.6 Information Management Technology (IMT)

4.6.1 GP Information Technology

4.6.1.1 The proposed imaging system should have 'user access authentication' mechanism to ensure that all instances of access to any personal confidential data are auditable against an individual.

4.6.1.2 Where data/images are transferred electronically both between scanner and provider and between providers from different organisations, this must be done strictly in adherence with **NHS Secure Data Transfer Regulations**, ensuring all communications are appropriately encrypted and secured.

4.6.1.3 Provision of digital data between the Provider PACS systems should be through the Image Exchange Portal (IEP) to other providers, or in clinical circumstances that require the transfer of the image to support the safe treatment of the patient.

4.6.1.4 In the event of the cancellation of the contract (for whatever reason) arrangements must be in place to ensure data is stored securely and made appropriately available in accordance with Data Protection Legislation. "Where necessary, arrangements should also be in place to enable the transfer of the data/images to a new supplier. The Provider will also be required to maintain systems to allow continued access, in a timely manner, to all of the patient information, images and associated patient records.

4.6.2 Digital Interoperability

4.6.2.1 The system supplier must have the ability to integrate with order communications systems (OCS) such as T-Quest or Sun-quest which is predominantly used by GPs and acute providers within North Central London to enable bidirectional communication of patient information, clinical and diagnostic decision-making, the progress of the DI procedure and image report status between the clinician and the diagnostic imaging service.

4.6.2.2 There should be a common unique identifier between the new system and the order communications system. It is expected that the records will be shared between organisations (primary care and acute) and as such it is desirable that the NHS number (preferably verified) is the primary identifier.

4.6.2.3 In secondary and tertiary care, the patient administration system (PAS) such as (Cerner Millennium, Medway, Silver link & EPIC) usually provides the patient master index of patient demographics (name, date of birth, sex, address, PAS number, NHS number). It also holds the information regarding the patient's location and their responsible consultant at a particular point of a clinical episode. In primary care, the relevant GP system (EMIS, Vision, System -One) will fulfil the same function.

4.6.2.4 The systems must be integrated to enable patient registrations, updates and merges to be exchanged. These processes are catered for by standard health level 7 (HL7) transactions incorporated within the Integrating the

Healthcare Enterprise (IHE) scheduled workflow and patient information reconciliation profiles.

4.6.2.5 In order for the system to provide sufficient intelligence to enable radiologists, radiographers and other DI staff to vet and prioritise requests (orders), a feedback loop is necessary to update the referrer as to the progress of the request.

4.6.2.6 It is also desirable for the referrer and DI staff to be able to access supplementary clinical information from the EPR (if available), relevant prior imaging history, including reports and images, and relevant pathology results from within the electronic requesting system. Ideally the system will have sufficient intelligence to 'pull' certain relevant information from other systems.

4.6.2.7 The new system should have a common user interface and consistent display parameters across the integrated order communications system, RIS and PACS are essential to ensure effective and safe requesting, vetting, scheduling and reporting.

4.6.2.8 The Provider is expected to work in partnership with secondary care providers in NCL to facilitate;

- The timely transfer of images alongside referrals from GPs to acute providers to simplify the GP referral process.
- It is mandatory on the Provider to establish a robust relationship with all stakeholders (GP and Acute providers) in order to design and implement image transfer pathways/protocols that would ensure images are available for the patient's clinical consultation following a referral.

4.6.2.9 The new system should also deploy the use of IHE standards to integrate with other healthcare digital solutions (such as Cerner's Health Information Exchange (HIE) which is the NCL digital interoperability system for real-time information transaction between disparate healthcare systems in North Central London and the wider London).

4.6.3 Enterprise Information Interoperability for Enterprise Image Capture

4.6.3.1 The system supplier should be able to adopt the new HL7 FHIR standard. A Web API, HL7 FHIR is the preferred mechanism to integrate with different devices than HL7 v2.x messaging and DICOM interfaces. Other alternatives are:

- A URL from the electronic health record (EHR) that launches the image capture application/device, with information in the parameters, in context is another option.
- Another method is to use HL7 messaging to populate a vendor neutral archive (VNA) database with patient information, and use an API to get the necessary information.

4.6.4 Metadata and Supporting Information

4.6.4.1 The proposed system should reliably capture the information that goes with the image(s) such as notes, anatomy info, findings, etc. In Digital Imaging and Communications in Medicine software (DICOM), the header of the SOP Class object specifies where this metadata goes.

4.6.4.2 There should be a defined format and data scheme, with a clear meaning (Without the information structure that DICOM provides, the definition of the metadata schema is left to be defined by the implementing vendor).

4.6.4.3 The proposed system should also collect operational data, for use in analytics and process improvement.

4.6.5 Consistent Terms

4.6.5.1 The new system should have a common schema, with consistent use of terms within the schema to prevent unnecessary mapping or the deployment of a secondary terminology integrating service.

4.7 Health Records, Data Protection, Caldicott Guardian, Etc.

4.7.1 Health Records

4.7.1 For all patients, the Provider will create, maintain and retain service user health records, such as patient records, notes, recorded telephone conversations (if applicable), etc. The Provider will retain these records for the periods of time identified in law.

4.7.2 The Provider will use service user health records solely for the execution of the Provider's obligation under the contract. Each patient will be given full and accurate information regarding his/her treatment and The Provider will evidence that in writing in the relevant service user health record.

4.7.3 Subject to guidance from Department of Health, Department for Public Service and Administration, etc., the service user health records must include the verified NHS number.

4.7.4 The Provider shall, without prejudice and relating to Patient Information, comply with the highest available CNST standard relating to the creation, maintenance, confidentiality, security, retention and disposal of Patient Information.

4.7.2 Data Protection, Freedom of Information and Transparency

4.7.2.1 The Provider and commissioners have duties under the Data Protection Act (1998) and Freedom of Information Act (2000) to give all reasonable assistance to each other where appropriate or necessary to comply with such duties. The Provider is expected to assist the commissioners in all freedom of information requests.

4.7.2.2 The Provider must achieve a minimum level two performance against all requirements in the relevant NHS Information Governance Toolkit applicable to it. The Provider will also ensure that it puts in place and maintains an information security management accreditation appropriate to the Services and the obligations placed on the supplier under this contract.

4.7.2.3 To the extent that The Provider is acting as a data processor on behalf of the commissioners, the Provider will comply with the data protection terms set out in the contract. The Provider shall report all incidents of data loss,

breach of confidence and information security in accordance with Department of Health and the NHS England and Health and Social Care Information Centre Guidelines (e.g. HSCIC Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation, June 2013)

4.7.2.4 The commissioners reserve the right to send suitably qualified staff to audit the Provider's compliance and/or for the Provider to provide the commissioners with evidence of its compliance with reasonable notice.

4.7.2.5 Where any personal data is processed by any subcontractor of the Provider in connection with this contract, the Provider shall ensure that such subcontractor shall comply with the relevant data confidentiality, protection and information security obligations set out in this specification and the main contract as if such subcontractor were the Provider.

4.7.3 Caldicott Guardian and Senior Information Risk Owner

4.7.3.1 The Provider must have a Caldicott Guardian and an information governance lead able to communicate with the Provider's board who will take the lead for information governance and from whom the Provider's board will receive regular reports on information governance matters including, but not limited to, details of all incidents of data loss and breach of confidence.

4.7.3.2 If the Provider replaces its Caldicott Guardian or Senior Information Risk Owner at any time during the term of the contract, it must promptly notify the commissioners of the identity and contact details of such replacements.

4.7.3.3 The provider must have a robust Risk Management system in place which enables the provider to identify and record all incidents and near misses, irrespective of harm. The provider will must have a process in place to investigate all incidents and near misses, using Root Cause Analysis (RCA) methodology, and provide a quarterly report identifying themes and learning which has resulted from the incident and / or near miss.

4.7.3.4 The provider must have the capacity and capability to identify incidents which meet the Serious Incident (SI) criteria as described in the 2015 NHSE Serious Incident Framework. The Framework applies to Serious Incidents which occur in all services providing NHS funded care, including independent providers where NHS funded services are delivered.

4.7.3.5 The principles and processes associated with robust Serious Incident management, must be endorsed within an organisation's Incident Reporting and Management Policy. Serious Incidents must be recorded on STEIS within 2 days of being identified, and the lead commissioner notified via phone or email. The provider will undertake and complete the investigation as per the SI Framework

4.7.3.6 Further, where attendance at any investigation meetings is required as a result of a radiology report discrepancy issued by the Provider, the Provider must send a representative.

4.8 Medicines Management

4.8.1 The Provider should have in situ a protocol for dealing with medical emergencies.

4.9 Staffing

4.9.1 The Provider shall without prejudice ensure and able to provide evidence if required, that all staff carrying out activities:

- Have the requisite training, qualifications and professional registrations e.g. NMC, HCPC required to deliver the service
- Are able to diagnose clinically significant or serious pathology identified by the activity and escalate;
- Have performed the minimum required number of diagnostic investigations as specified;
- Are registered with or hold the relevant professional qualifications for that diagnostic investigation as specified by the competent authority for that diagnostic investigation or recognised voluntary registration scheme where appropriate;
- Are on the relevant GMC specialist register for the relevant diagnostic investigation, as described in the clinical specifications (See Appendices)
- Staff have English as a first language or have passed a suitable English language examination to the level requirement set out on the Health and Care Professions Council website http://www.hcpc-uk.org/apply/international/requirements;
- For staff other than where engaged solely in tele-reporting, have a current valid basic life support certificate; and
- Have relevant clinical competencies in terms of skills and knowledge base as set out in the UKCC approved National Occupational Standards available at http://www.skillsforhealth.org.uk/.

4.9.2 For Provider personnel providing Radiology Reports:

- The Provider must ensure reports are provided by General Medical Council (GMC) registered radiologists who are UK trained.
- The Provider must provide the Commissioner with a listing of all the practitioners providing reports and reflect these in the Approved Panel. The Provider must maintain this list and provide periodic updates to the Commissioner as recertification and relicensing takes place and new examiners/practitioners join the pool of practitioners used by the Provider to provide radiology reporting to the Commissioner. Where the Provider uses a practitioner who is also an employee of the Commissioner then the Provider must disclose this to the Commissioner.
- For in-hours/elective reporting, the Provider must be able to provide on request and maintain:
  - An up to date Curriculum Vitae (CV) of staff producing radiology Reports; and
  - Evidence of 5 yearly GMC revalidation.
- Where the Provider uses a practitioner who is also an employee of the Commissioner then The Provider must disclose this to the Commissioner.
- The Provider must ensure that any individual issuing a radiology Report is appropriately trained and possesses sufficient relevant technical expertise for the specific type of report being requested. Unless agreed

between the parties as a complex Report all Reports will be treated as standard Reports and will be priced accordingly.

- The Provider must ensure that radiologists and support personnel have a full working knowledge of the English language and have completed an accredited assessment of English proficiency when English is not their first language per the relevant GMC guidelines. Evidence must be provided by the Provider on request from the Commissioner.
- For Sub-Specialist Reporting, the Provider is required to provide Radiologists qualified as outlined earlier of this Section and in addition, be able to evidence either a recognised Sub-Specialist clinical fellowship or a Sub-Specialist interest.

4.10 Equality of Access

4.10.1 The Provider shall in relation to the services:

- Not discriminate between patients on the grounds of age, sex, ethnicity, disability, or any other non-medical characteristics;
- Understand that some patients may need a longer appointment time to accommodate a disability, restricted movement etc.
- Implement Royal National Institute for the Blind and Royal National Institute for the Deaf guidance to ensure patients who have disabilities and/or communications difficulties are able to receive the services (available from www.rnib.org.uk and www.royaldeaf.org.uk); and
- Supply at no cost professional translation services and translations of materials available to NHS patients describing relevant procedures for the commonest ethnic languages of NHS patients most likely to use the services as recommended by the NHS representative.

4.11 Patient Dignity and Respect

4.11.1 The Provider shall:

- Ensure that the facilities allow NHS patient privacy and confidentiality;
- Allow NHS patients to have their personal clinical details discussed with them by a person of the same gender, where required and if reasonably practicable; and
- Provide a chaperone of the same sex as the patient for intimate examinations and on request for all other examinations. This person shall have had training in the duties of a chaperone.

4.12 Obtaining Consent

4.12.1 The Provider must operate a policy to comply with good clinical practice, good health and/or social care practice and the law. In particular, The Provider will comply with:

- Good Practice in Consent Implementation Guide: Consent to Examination or Treatment (Department of Health, 2001).
- Health Service Circular 2001/023, ‘Good Practice in Consent’ (NHS Executive, 2001)
- Consent: Patients and Doctors Making Decisions Together (GMC, 2008 (Subject to consultation and refresh in 2018 and 2019) www.gmc-uk.org/ethical-guidance .
- National Institute for Health and Care Excellence www.evidence.nhs.uk

4.12.2 Prior to commencing an activity, the Provider shall obtain consent from the NHS patient for the provision of such activity in accordance with the consent requirements.

4.12.3 Where an NHS patient has been assessed by the Provider as unable to give consent to the relevant activity, the Provider shall act in accordance with the consent requirements which includes acting in the NHS patient's best interests.

4.12.4 If an NHS patient refuses to give consent for the procedure and also for sharing of data with the reporting Radiologist, the referrer or any other Healthcare professional involved in the patients care, then the diagnostic test will not be carried out (or if proceeding with the activity is not in the NHS patient's best interest) and the Provider shall notify the referrer.

4.13 Clinical Safety & Medical Emergencies

4.13.1 For all services the Provider shall ensure that sufficient staff with appropriate skill, training and competence are available to maintain patient safety at all times when the services are being delivered;

4.13.2 The Provider shall ensure that it has at each facility adequate equipment (e.g. cardiopulmonary resuscitation (CPR), automated defibrillation) to deal with medical emergencies without prejudice to its obligations under this agreement, has procedures to deal with medical emergencies, including without limitation, BLS treatment, stabilisation, arranging transfer to an appropriate NHS Trust which can provide the level of critical care required and any other steps that could reasonably be required to minimise the adverse consequences of the medical emergency, including using, where appropriate, locally agreed transfer protocols where these exist always having regard for the fact that the activities to be carried out under this agreement are not high risk activities.

4.13.3 For the avoidance of doubt, the following are not high risk activities, and do not require the provision of ALS (ACLS) cover:

- Radiological imaging that does not include biopsy or intravenous contrast;
- Physiological measurements that do not involve a stress/exercise test; and
- Pathology tests (i.e. phlebotomy or Point of Care Testing).

4.14 Infection Control and Decontamination

4.14.1 The Provider shall ensure that at all times it:

- Has appropriate procedures in place to control and prevent the transmission of infection;
- Uses its best endeavours to take all steps required to prevent the spread of any infections to patients including but not limited to:
  - All recommendations in the Health Improvement and Protection Bill and the accompanying Code of Practice for the Prevention and Control of Healthcare Associated Infection 2006 (as amended, supplemented or updated from time to time) and the latest relevant infection control guidance recommended by the Medicines and

Healthcare products Regulatory Agency (MHRA) and the Health Protection Agency and any successor bodies: and
- The Professional Specialist Advisory Bodies and Associations;

- Has effective decontamination protocols, including cleaning, sterilisation, disinfection, and (if appropriate destruction) of all equipment used in the delivery of the services and in accordance with manufacturer's instructions and MHRA or Health Protection Agency recommendations;
- Minimises the risk of patient to patient or staff to patient transfer of infectious agents that may harm patients

4.14.2 The Provider shall, without prejudice retain a record to identify sources of any infection acquired by patients at the facility of which The Provider is or becomes aware.

4.14.3 The Provider will audit decontamination procedures in accordance with National Minimum Standard and as agreed with the NHS representative from time to time.

4.14.4 The Provider will have written infection control procedures in accordance with National Minimum Standard and as agreed with the NHS representative from time to time.

4.14.5 The Provider shall, at all times, designate a member of staff at the facilities who shall be responsible for all administrative tasks relating to decontamination and control of infection (the Infection Control Officer). The Provider shall appoint an appropriately qualified infection control nurse to provide assistance and support to the Infection Control Officer.

4.14.6 The Provider shall ensure that all infection control related incidents of transmission of infection to patients of which the Provider is or becomes aware, are recorded and reported as part of the reporting requirements in accordance with this agreement.

4.14.7 The Provider shall participate in all national infection surveillance programmes including MRSA bacteraemia, surgical site infection and clostridium difficile surveillance.

4.14.8 Upon the occurrence of an infection event of which the Provider is or becomes aware, the Provider, or the Infection Control Officer acting on behalf of the Provider, shall:

- Inform the specialist microbiologist and seek his/her advice;
- Initiate the necessary investigation into the event;
- Notify the consultant for communicable disease control;
- If appropriate, register the infection in the national surveillance programme;
- Request the support of, without limitation, neighbouring NHS microbiology laboratories and the Health Protection Agency where the future management of infections is considered to require additional specialist support; and
- Take all appropriate action including without limitation:
  - Obtaining specimens;
  - Administering treatment including prophylactic treatment to the patient and others including without limitation, other patients, visitors, staff and Providers and the public at large at that facility;

- Implementing appropriate isolation arrangements for the patient or others;
- Closing the facility to further admissions;
- Procuring specialised cleaning or decontamination of the facility including its contents; and
- Acting in accordance with good clinical practice and national minimum standards.

4.15 Services other than Diagnostic Services

4.15.1 The Provider shall provide (or procure the provision of) the services other than diagnostic services at the facilities to ensure the Provider is able to provide the diagnostic services in accordance with the terms of this agreement.

4.15.2 The Provider shall provide (or procure the provision of) the services other than diagnostic services in accordance with:

- The highest level of standards that can be derived from the standards and regulations
- In a manner which is consistent with, and which facilitates the delivery of the Diagnostic Services to the standard required by this Agreement; and
- The National Minimum Standard or standard acceptable to the Care Quality Commission.

4.16 Education

4.16.1 The Provider shall on an ad-hoc basis support delivery in association with Commissioners of:

- Referrer education training including website usage
- Patient education on appropriateness of imagining
- Patient education in regards to healthy living and lifestyle choices

5. COMMON SERVICE REQUIREMENTS

In complying with this section, the Providers attention is also drawn to Information Management Technology (IMT) requirements outlined in clause 4.16.

5.1 Diagnostic Services Required

5.1.1 The Provider shall provide at the request of the referrer, reports being either:

- Investigation Output only; and/or
- Diagnostic Reports
- Technical Reports

5.2 Referral Methods

5.2.1 Referrals shall be made by the referrer to the Provider in accordance with the agreed local referral process, using the required referral template/format.

5.2.2 Referrals will be by any of the following methods:

5.2.2.1 e-Referral System (or other web-based system)

5.2.2.2 Secure e-mail system

5.2.2.3 Any other local method that may be specified by the commissioner from time to time

5.2.2.4 Telephone communication in advance to the Provider, who will then arrange a patient appointment directly with either the NHS patient or the referrer, depending upon the local patient care pathway, which will then be followed by documented referral (as outlined in 5.3.2.1, 5.3.2.2 or 5.3.2.3 or in writing)

5.2.3 The Provider shall accept a referrals by web-based systems, secure e-mail, other local method (agreed from time to time with the commissioner) or telephone (followed up as outlined in 5.3.2.1, 5.3.2.2 or 5.3.2.3 or in writing)

5.2.4 The Provider shall accept a referral irrespective of the method of referral used by the referrer;

5.2.5 The referrer will become bound to the Provider on the terms contained therein, by accepting the offer to have the Provider accept referrals on the terms pf the Referral Terms and Conditions.

5.3 Patient Referral Information

5.3.1 The patient referral information shall be sent with the referral by the referrer.

5.3.2 Where appropriate, referrals shall include:

5.3.2.1 Clinical data

- Type of diagnostic investigation requested for the NHS patient including any special instructions where applicable e.g. anatomical area(s) to be investigated, clinical question(s) prompting the investigation;
- Pertinent clinical information including indications, pertinent history, and provisional diagnosis if available;
- Details of any previous treatment including medications given to the NHS patient for the condition;
- Relevant previous investigations and reports (including photocopies of results if appropriate);
- Details of any relevant associated medical conditions (e.g. insulin dependent diabetes);
- Details of all treatments or medication that could cause a contraindication to the diagnostic investigation;
- Details of current medications and any other known allergies;
- LMP or pregnancy/breast feeding status of all females of child-bearing age prior to X-ray or nuclear medicine studies together, if required, with a pregnancy test result to confirm negative status, in accordance with the Joint Royal College of Radiologists/College of Radiographers/ National Radiological Protection Board Guidance entitled “Advice on Exposure to Ionising Radiation during Pregnancy” published in 1998 (as amended, supplemented or updated from time to time);
- For DXA, prior fragility fractures, prior bone trauma/fractures or surgery, medication e.g. glucocorticoids, thyroid replacement, phenytoin or heparin;
- Any MRI contraindications;

- Confirmation that the NHS patient has no known contraindications to the proposed investigation;
- Any special needs (e.g. interpreter required, disabilities requiring special manual handling, carer support);
- Details of community support services in place, if appropriate (e.g. ambulance services, carer support);
- For imaging diagnostic investigations, previous images of the same/similar anatomical area, of no more than 3 years old, in electronic format where such previous images are available. No hard copy film will be provided;
- Date and time of referral;

5.3.2.2 Administrative data

- Basic contact information for the NHS patient including: full name (and title), the name of the parent or carer (if appropriate), sex, NHS Number, date of birth, next of kin, address and postcode, home and daytime telephone number, evening telephone number, mobile telephone number and/or e-mail contact details for the NHS patient if available; and confirmation that consent has been obtained to use each of these contact modalities, including text message;
- Name, address, NHS e-mail address and telephone number of the referring clinician and any other healthcare professionals who are to receive copies of the report;
- The date of the NHS patient's initial appointment with the NHS patient's GP or referrer;
- Referral CCG code, referring clinician practice code, NHS patient's GP telephone number, NHS patient's GP NHS email address and NHS patient's GP address;
- The name, address and telephone number of the NHS patient's choice of next of kin;
- Any relevant social or domestic history, including mobility, home environment and family circumstances; and
- Any relevant factors influencing the NHS patient's ability to receive and responding to communications including without limitation lack of fluency in English, visual or auditory impairments etc.

5.3.3 If a Referral does not have all the patient referral information required The Provider shall:

5.3.3.1 Contact the referring clinician for the required information within one working day of receipt of the referral;

5.3.3.2 Make enquiries on the NSTS or its successor the Personal Demographic Service or the NHS Care Records Service as it becomes available in the future; and

5.3.3.3 Contact the NHS patient to obtain the necessary information prior to conducting the activity, if the information cannot be provided by the referring clinician and is not of a clinical nature.

5.3.4 The Provider may only refuse to accept a referral and not complete the activity if the patient referral information and:

5.3.4.1 To proceed with the activity would be clinically unsafe; or

5.3.4.2 The Provider does not have sufficient patient referral information to ensure that the report can be delivered back to the referrer by the report by date.

5.3.5 If The Provider does not receive the Patient Referral Information it requires from the referrer within 3 days of a request being made to the referring clinician for such necessary patient referral information and it is not possible otherwise to obtain the required patient referral information from the NHS patient, then the Provider shall refer the NHS patient back to the referrer, with a written explanation of the patient referral information that was not provided.

5.3.6 All requests for additional patient referral information by the Provider shall be made via NHS.net initially.

5.4 Relative Contraindications

5.4.1 The referrer shall add known contraindications to the referral form.

5.4.2 If the NHS patient is known to be pregnant or have any other contraindication, the Provider shall as part of the process of obtaining consent from the NHS patient explain to the NHS patient the potential risks to the foetus or any other relevant potential risks and clinical benefits of the activity before proceeding with the activity.

5.5 Confirmation of Patient Attendance

5.5.1 The Provider shall:

5.5.1.1 Confirm to the referring clinician the receipt of the referral by no later than the next business day after the receipt date; this process relates to the triage of referrals. The Provider will look at the referral and decide if the diagnostic test is appropriate if not will return to the referrer advising that that this was an incorrect test and then suggest/refer for the correct one.

5.5.1.2 Contact all NHS patients within (2) business days of the referral date to agree a date, time and the location of the facility for each patient appointment date, or confirm the date and time of the patient appointment in the case of an appointment booked by the referring clinician;

5.5.1.3 If the NHS patient cannot be contacted at the first attempt, make reasonable efforts, including not less than four (4) attempts over two (2) consecutive business days, at different times at least two (2) hours apart to contact the NHS patient to arrange the patient appointment before the end of the maximum period;

5.5.1.4 Offer the NHS patient alternative times for the patient appointment;

5.5.1.5 Offer NHS patients a choice of appointment date and time at the point of booking a patient appointment;

5.5.1.6 If practical, where an NHS patient requires multiple diagnostic investigations, arrange the patient appointments (or as many as is practicable) on the same day and in the same facility;

5.5.1.7 Confirm in writing (where practicable) to the NHS patient the agreed date and time for the patient appointment within (2) business days of agreeing the date or if it was not possible to agree a date and time for the patient appointment contact the referring clinician within (1) business day. The Provider shall establish a referral format that enables GPs to indicate that the patient can be booked outside of the 10 working day period at their convenience, e.g. where about to go on holiday;

5.5.1.8 Provide to the NHS patient at the time of making any and all patient appointments for an activity a contact telephone number which is answered between the hours of 8am and 8pm during weekdays and have an answering service for all other weekday hours and weekends to answer NHS patient questions and to receive cancellations;

5.5.1.9 Take all reasonable steps to minimise the number of DNAs;

5.5.1.10 If practicable, having regard to the period between the making of the patient appointment and the activity being carried out issue (2) reminders to all NHS patients, by telephone, e-mail or SMS text message, 72 and 24 hours before the time of the patient appointment to:

- Confirm their attendance; and
- Answer any outstanding questions;

5.5.1.11 If an NHS patient does not attend a patient appointment then The Provider shall:

- Make reasonable efforts, including not less than 3 attempts over 2 consecutive business days, at different times to contact the NHS patient to rearrange the patient appointment as soon as possible and in any event before the end of the maximum period. It was agreed that contact may be made via phone, text or any other suitable means in the first instance and then if contact has failed, that the Provider should
- On the third business day, inform the referrer via letter of the patient non-attendance

5.5.1.12 If an NHS patient cancels their patient appointment then where such cancellation is made:

- By telephone, the Provider shall arrange the patient appointment as soon as possible and in any event before the end of the maximum period; or
- By post, email or telephone message, the Provider shall make reasonable efforts, including not less than (3) attempts over (2) consecutive business days, at different times to contact the NHS patient as soon as possible and in any event before the end of the maximum period.

5.6 Appointment Preparation

5.6.1 The Provider shall, if appropriate, before beginning a diagnostic investigation, provide verbal and written information to the NHS patient to explain:

- How to prepare physically, mentally and socially for the diagnostic investigation, including potential late complications and how to seek help if they occur;

- Appropriate advice about preparations for the activity including by way of example prescribed sedatives before the diagnostic investigation or discontinuance of treatment;
- The diagnostic investigation procedure/process;
- Any preparation the NHS patient should make before attending the facility, including but not limited to:
  - Suitable attire;
  - Special instructions (e.g. fasting, full bladder etc.);
  - Restrictions on the NHS patient's activities after the diagnostic investigation (e.g. sedation, driving, drinking);
- The likely duration of the diagnostic investigation;
- The location of the facility; and
- Directions to the facility (including details of car parking and public transport).

5.7 Pre-Diagnostic Investigation Assessment

5.7.1 Before commencing any activity, the Provider shall:
- Ensure that the medical exposure for patients to ionising radiation is justified and authorised in accordance with the IR (ME)R;
- Assess the NHS patient to identify medical contraindications to the diagnostic investigation; and
- Request authorisation from the referring clinician for the Provider to proceed with a different or additional diagnostic investigation if a different or additional diagnostic investigation is clinically more appropriate, in accordance with good clinical practice.

5.7.2 The Provider shall refer back to the referring clinician, within one working day of the Provider becoming aware with an explanation of the reason why NHS patients who are unsuitable to receive the activity for which they have been referred after explaining the reasons to such NHS patient.

5.8 Performing the Procedure/Investigation

5.8.1 The Provider shall commence the activity within 15 minutes of the agreed patient appointment time if the NHS patient arrives on or before the agreed patient appointment time.

5.8.2 The Provider shall perform the diagnostic investigation and ensure that acquisition protocols:
- Yield high diagnostic value output with minimum artefacts; and
- Use the lowest possible radiation dose for radiology activities in accordance with the IR(ME)R.

5.8.3 When clinically appropriate, the Provider shall proceed to a therapeutic diagnostic investigation (e.g. therapeutic endoscopy).

5.9 Emergency Escalation During or After Activity

5.9.1 The Provider shall, without prejudice if appropriate during the course of the activity or immediately after, and in any event, within 2 hours of becoming aware of any serious condition discovered during the activity (or if the condition for which the NHS patient is referred is, on investigation, found by the Provider to be more serious than the referring clinician indicated at the

time of referral) inform the referring clinician by telephone and in accordance with Urgent Referral Protocols:

- If necessary, for medically urgent conditions (e.g. brain abscess, cauda equine) refer and organise the transfer of the NHS patient to the most appropriate NHS Trust to ensure the effective urgent treatment of the new or more serious condition diagnosed, and supply a copy of the report for the NHS patient to the referring clinician and receiving clinician and the medical facility to which the NHS patient has been transferred, within 2 hours of discovering the medically urgent condition, and in any event in advance of or at the time of the NHS patient being seen by the receiving clinician; and
- In the case of malignancy, suspected cancer or other clinically serious findings identified by the activity, supply a copy of the report for the NHS patient to the referring clinician within (1) business day following discovery of the condition.

5.10 Patient leaving the facility

5.10.1 The Provider shall:

- Allow NHS patients to leave the facility if in the professional opinion of the Provider they are fit to do so;
- Make appropriate arrangements in accordance with any local referral procedures to have NHS patient transferred to a suitable local community facility, if the Provider acting reasonably considers them unfit to be sent back to their current residence; and
- Contact the NHS patient concerning further clinical issues only via the referring clinician following exit.

5.11 Quality Requirements of reports: Type & content

5.11.1 The Provider shall supply a diagnostic report or a technical report as specified by the referrer to the referring clinician, and any other clinicians identified in the referral.

5.11.2 The diagnostic report as a minimum shall contain the following information:

- An accurate, relevant description and interpretation of the key findings;
- A precise diagnosis whenever possible;
- A differential diagnosis when appropriate;
- Suggestions for follow-up, intervention, or additional or repeat diagnostic studies, in accordance with good clinical practice;
- Any significant NHS patient reaction or details of clinical complications;
- All information, including negative information, which is pertinent to the clinical issues raised in the referral for the activity;
- Comparative information with previous examinations if the Provider has access to previous examinations.

5.11.3 If the reporter is suggesting a secondary care referral, this should be an option, rather than a must do, due to the differing number of pathways within NCL. A reference to clinical correlation in the report may be helpful.

5.11.4 General information required for reports shall include:

- A sample image (or images) which illustrates the diagnosis unless the referring clinician requests a form of report transmission which is not capable of supporting an embedded image (or images) in which case

The Provider must provide clear instructions in the report to the referring clinician as to the method of accessing such image (or images);

- Full name of the NHS patient, NHS number, sex, date of birth, or other pertinent identification number;
- Address and postcode of NHS patient;
- Name of the referring clinician;
- Name of healthcare professional who carried out the activity and relevant professional qualifications (excluding MRI and X-ray, where only reporting clinician details are provided);
- Name and qualifications of the reporting clinician(s);
- Name or type of activity (including any applicable HRG or other clinical code for it);
- Date(s) of activity including examination, dictation and transcription;
- Normal ranges for laboratory and physiological measurement;
- Management plan programme.

5.12 Quality requirement of reports: General

5.12.1 The Provider shall produce reports that are:

- Securely delivered so as to preserve confidentiality of patient records irrespective of the method of delivery of the report;
- Identifiable as being prepared by a single individual with appropriate qualifications and authenticated whether by a recognised electronic signature or a written signature with the name that is printed and legible;
- Authenticated by a doctor or other healthcare professional with appropriate professional registrations
- Interpreted, produced and reported on by an appropriate subspecialty reporting clinician for MR and X Ray activities;
- Produced by reporting clinicians who have achieved minimum competency standards
- Complete, precise, relevant, clear, unambiguous, accurate, and tailored to the skill and experience of the referring clinician category;
- Proof read carefully to avoid typographical errors, deleted words, confusing or conflicting statements; and
- Written in English, and at least to the standard of International English Language System (ELST) level 7; and
- In accordance with professional medical conventions and terminology widely accepted in the NHS.

5.13 Quality requirements of activity output: Communication, Distribution & Timing

5.13.1 The Provider shall:

- Ensure the referring clinician receives the report (and associated scans) by the report by date, defined as:
  - For non-urgent referrals within a maximum of 18 days from date of referral (i.e. scanning within 15 days from referral + 3 days to draft report)
  - For urgent referrals within a maximum of 8 days from date of referral (i.e. scanning within 5 days from referral + 3 days to draft report)

- Where a patient chooses an appointment outside of the 10 day window, the Providers report (and associated scans) shall be available within 3 days of the appointment;
- Communicate any unusual, unexpected, urgent, or clinically significant findings that may require immediate or urgent clinical decisions to the referring clinician and referring Health Service Body;
- Ensure that the healthcare professional who prepared the report (or a deputy healthcare professional of equal standing and who has access to and understands all the relevant information concerning the report) is available for consultation in English with the referring clinician and receiving clinician by telephone within 2 hours of a request for consultation being made where clinically urgent, and by the next business day if non-urgent, and in the case of an NHS patient diagnosed with cancer make the healthcare professional who prepared the report available to consult in person, or by high speed video phone, with the multi-disciplinary team treating the NHS patient as and when required by the multi-disciplinary team;
- Communicate to the referring clinician any discrepancy between an emergency or preliminary report and the final written report; and
- Supply a copy of the report to:
  - The referring clinician;
  - Any other healthcare professional identified in the referral as requiring a copy;
  - Any acute secondary care facility or receiving clinician, to which the NHS patient has been transferred and in advance of or at the time of the arrival of the NHS patient; and image transferred.

5.14 Presentation and Discussions at Multi-Disciplinary Team Meetings

5.14.1 The Provider may on an ad-hoc basis (with a minimum of 5 days' notice):

- Be requested to participate in a multi-disciplinary team meeting or case conference, where NHS patients have a definitive diagnosis of cancer, and their management requires the input of the reporting clinician to provide clinical expertise into such a multi-disciplinary team meeting; and
- Have appropriate technology in place to facilitate their input, should they not be in a position to attend the meeting in person.

5.15 Quality Assurance

5.15.1 The Provider shall:

- Be clinically and managerially responsible and accountable for any activity carried out on the NHS patient;
- Operate an effective comprehensive, clinical governance system with clear channels of accountability and supervision that reduces the risk of clinical system failure;
- Put in place effective quality assurance systems to ensure the false positive and false negative rates of all diagnostic investigations are within acceptable limits and to minimise the need for repeat activity due to poor quality report;
- Ensure the NHS patient receives the appropriate activity and the appropriate report is produced for each NHS patient;

- Continuously monitor clinical performance and evaluate unexpected clinical complications/adverse events arising from any activity. This shall also include, where relevant:
  - Adequacy of tissue sample and accuracy of pathological reports from procedures performed by staff; and
  - An evaluation of the accuracy of investigation interpretations and the contribution of the report to answering the clinical question posed, the clinical appropriateness of examinations undertaken and any further investigations suggested;
- Audit clinical care against clinical standards, and use appropriate formal methods such as root cause analysis for untoward incidents;
- In addition initiate any appropriate correction methods/or other rectification plans as soon as possible to reduce any clinically significant interpretation discrepancies, identified by clinical audit, double reporting or any other quality systems used by The Provider;
- For radiology activity, monitor and document any adverse exposure errors and investigate them in line with IR(ME)R;
- Have the ability to retrieve and send out a copy of any report including Digital Medical Images within (1) business day of receiving a request for a copy of the report from a referring Health Service Body;
- Retain a copy of the report and any Digital Medical Images or other recordings as a permanent record of the activity being of sufficient quality and durability to be used for comparison with subsequent examinations, and enable third party healthcare professionals to confirm the report;
- Ensure all Digital Medical Images and Investigation Outputs are reliable, high quality, with minimal artefact, and capable of identifying any clinically significant pathology/findings that are present, within the limitation of the diagnostic equipment used in the activity, and are stored so as to retain all these characteristics;
- Have and maintain CPA quality assurance accreditation for laboratories, and NHS requirements for equipment used in activities;
- Maintain records that demonstrate repair and maintain equipment quality control, calibration, validation, and routine testing, in accordance with manufacturer's instructions/ recommendations and otherwise in accordance with the operating manual for the facility and also retain a record of all activities carried out to meet these obligations;
- Co-operate generally, and specifically, referrer to take copies of) any and all provider records relating to provider clinical governance to enable the referrer to audit and verify the clinical governance standards of The Provider.

5.15.2 In addition:

- The Services shall at all times be delivered consistent with best practice standards and to the reasonable satisfaction of the Authorised Officer (Clinical Lead of Imaging at the Commissioner);
- The Provider must ensure that the Services comply with the standards of the Royal College of Radiologists, all relevant rules and guidelines of the Care Quality Commission of the Department of Health and any appropriate law of the United Kingdom. Specifically the Provider is required to ensure it complies with NPSA Safer Practice Notice (16) 2007 and Royal College of Radiologists: Standards for the Communication of critical, urgent and unexpected significant radiological findings (2008);

- The Provider must demonstrate clinical governance procedures and ensure compliance with the Commissioner's governance policies in relation to the reporting of discrepancies.
- The Provider is required to develop and share with the Commissioner the relevant agreed policies required to deliver the Service, including updates following review;
- The Provider recognises the necessity for, and commits itself to, a philosophy of continuous improvement in quality of services and professional standards;
- The Provider recognises the need to actively engage with all Commissioners to understand local systems and processes for delivery and quality assurance.

5.16 Clinical Audit

5.16.1 The Provider shall:

- Ensure that an independent clinician, at least weekly, and using a double blind method, double reports a minimum of 10% in relation to MRI and X Ray and 5% for all other modalities of each reporting clinicians:
  - Diagnostic Reports; and
  - Technical Reports that are not part of the Investigation Output;
- Report promptly any clinically significant diagnostic reporting errors to the NHS representative and institute all necessary immediate corrective plans and rectification plans immediately thereafter; and
- Implement a monthly report of clinical performance by each clinician, showing volume of reports undertaken in the period.

5.17 Responsibility for Repeat Activity

5.17.1 The Provider shall (at its own cost) repeat as soon as possible, any activity which is incorrectly performed and/or where the output results in an inadequate report.

5.18 NHS Patient Experience & Referrer Satisfaction Survey

5.18.1 The Provider shall:

- Ask a minimum of 90% (ninety percent) of NHS patients selected at random from each site, from all categories of activity (for each contract month during which the facility is performing activities) to complete a Picker Institute/Healthcare Commission standardised patient experience questionnaire quarterly, or such other similar questionnaire as the NHS representative may reasonably agree from time to time;
- Ask a minimum of 10% (ten percent) of referring clinicians to complete an satisfaction questionnaire annually; and
- Report on the outcomes of the satisfaction surveys to the NHS representative within 45 business days of issuing the surveys or publication of the report (whichever is sooner) and co-operate with the NHS representative to implement all appropriate initiatives to improve NHS patient and referring clinician satisfaction with the services.

5.19 Communications

5.19.1 Communications to the referring clinician will be electronic via the Provider's nhs.net account or as requested by the referrer. Unusual or urgent reports will, where possible, be telephoned through to the referring clinician so that they can take the appropriate steps to follow up the patient, with a copy of the report, will be sent to the surgery.

5.19.2 Where the action is to be carried out by the referring clinician the patient will be given written instructions advising them to arrange an appointment (telephone or face to face) with their GP within 7 days to discuss the results of their investigation.

5.19.3 Where appropriate matters of an urgent nature, out of hours, should be escalated to the referring clinician out of hours service.

5.20 Training, education and research activities

5.20.1 On-going training and education must be given in order to ensure delivery of high quality, evidence- based care at all times. Annual audit and evaluation of the service will lead to improvements in care outcomes.

5.21 Supply, Maintenance and Installation of Equipment

5.21.1 The Provider will make ready the room for installation including surveying, electrical testing and supply, shielding, cooling system etc.

5.21.2 The Provider will be responsible for servicing and regular maintenance of all the supplied equipment and ensure the required testing of the equipment, electrical supplies and the cooling system.

5.22 Business Continuity

5.22.1 The service must have comprehensive arrangements for risk management and business continuity, including a Business Continuity Plan that will support continuation of service delivery in the event of emergencies.

6. CQUINs

6.1 CQUINs are not applicable to this contract/service specification.

7. KEY PERFORMANCE INDICATORS

In complying with this section, the Providers attention is also drawn to Information Management Technology (IMT) requirements outlined in clause 4.16.

7.1 Key Performance Indicators for the contract/service specification are outlined in Table B.

Table B: Key Performance Indicators

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Patient Reported Satisfaction of an overall good experience of the service.	(95%) report overall satisfaction with the service.	Patient satisfaction survey to be sent out to a	General Condition GC9

Patient Related Experience Measure Survey (PREMS) content to be agreed with commissioners		minimum of 90% of Patients, with a minimum response rate of 30%. These survey outcomes should be reported on a quarterly basis 75% to score % satisfied / very satisfied Quarterly Quality Assurance Report	
Percentage of referrals received via the e-Referrals System or email system.	(100%)	Monthly Performance Report.	General Condition GC9
Rejections – Total number of referrals rejected by Provider. Quarterly report to cover themes of reasons for rejections	(15%)	Monthly Quality Assurance Report	To work with commissioners to improve appropriateness of rejection.
Error Rate: Number of Patients who have a repeat diagnostic test as a result of poor quality imaging and reporting (expressed as a % of total activity)	Less than (1%) If 1% breeched independent review of this will be completed within 28 days	Monthly Quality Assurance Report Outcome of review for immediate implementation and report to commissioners of Remedial Action Plan (RAP)	General Condition GC9 + Repeat activity to be provided at no cost to the NHS.
Duplication Rate: Number of patients who have two or more of came diagnostic scan for the same referral reason	Total number of patients having duplicate scans. Total number of patients having duplicate scans for the same referral reason Number repeated due to image quality.	Monthly Quality Assurance Report	General Condition GC9
Provider will triage all referrals upon receipt within 2 days.	(98%) Number of referrals received triaged.	Monthly Performance Report	General Condition GC9

Initial contact to be made with patient within (2) days of triage of referral. If the NHS patient cannot be contacted at the first attempt, make reasonable efforts, including not less than four (4) attempts over two (2) consecutive business days, at different times at least two (2) hours apart to contact the NHS patient to arrange the patient	(98%) Total number of referrals accepted. Total number of patients contacted in 2 days. Total number of failed contacts in 2 days	Monthly Performance Report.	General Condition GC9 + Provider to provide patient scan at no cost to the NHS.
Report of the outcome of triage to be sent to referrer within 5 workings days of receipt of referral	98%	Monthly performance report	General Condition GC9
Reporting Clinicians requires a minimum of information for referrer to act on the image with clear rational for suggested outcome. For Camden MSK: Please send report **only** as recommendations will be made by Camden MSK Clinicians.	100%	Monthly Quality Assurance Report	General Condition GC9
Patient offered choice of location and day and time of appointment that is convenient to them.	(98%) of patients to be offered choice.	Monthly Quality Assurance Report	General Condition GC9
Non-urgent referrals: Investigation undertaken within 15 days of receipt of referral.	100%	Monthly Performance Report.	General Condition GC9
Urgent referrals: Investigation undertaken within 5 days of receipt of referral.	100%	Monthly Performance Report.	General Condition GC9
Report and image of investigation to be sent to all referrers	100%	Monthly Performance Report.	General Condition GC9
Report and image of investigation to be sent to referrer within 3 days of patient attending for diagnostic investigation.	100%	Monthly Performance Report.	General Condition GC9
Report and image to be sent to the referrer to be compatible with the latest interoperability systems.	100%	Monthly Performance Report.	General Condition GC9
Non-attendance: Percentage of referrals not completed due to patient DNA	No more than (2.5%)	Monthly Performance Report.	General Condition GC9
Non-attendance: Percentage of referrals not completed due to patient cancellation.	No more than 2.5%	Monthly Performance Report.	General Condition GC9
Provider cancellation of appointment either before or after Patient arrives for investigation.	No more than (0.8%)	Monthly Performance Report.	General Condition GC9 + Non-payment for non-investigation.
Patient waiting more than (15) minutes after appointment time before start of investigation activity (measured as a percentage of all Patients scanned).	No more than (5%)	Monthly Performance Report.	General Condition GC9

Complaints register to be provided every quarter.	No more than (5%) of complaints substantiated.	Monthly Quality Assurance Report	General Condition GC9
SI's to be reported as they are identified to lead commissioner as per SI reporting current mechanisms		Monthly Quality Assurance Report	
A GP satisfaction surveys will be designed and sent to all referrers annually to assess satisfaction with service and target response rate of 30% achieved.	85% satisfied or very satisfied with the service. 30% response rate	Monthly Quality Assurance Report (annual report)	General Condition GC9
Referral Rejections – Non-direct access referrals if not appropriate for the service will need clinical reasoning for rejecting with advice.	% referrals rejected with reasons	Monthly Quality Assurance Report	General Condition GC9

8. PERFORMANCE STANDARDS

In complying with this section, the Providers attention is also drawn to Information Management Technology (IMT) requirements outlined in clause 4.16.

8.1 The Provider will work within the Commissioners' quality and performance management framework. The Framework is not exhaustive and the Provider will work with Commissioners to develop this framework, introduce new indicators and, where necessary or required by commissioners, improve the scope and sensitivity of existing indicators.

8.2 Monitoring reviews against this Framework and specification will take place on a quarterly basis or the frequency as set out in the Framework.

8.3 In support of this Framework, the Provider and Commissioners will agree an annual programme of audits, which will be in addition to the national quality requirements. The Provider will report on those indicators or information requirement by the Commissioners. In time this process will link with the whole system so that audits process, and expected outcomes, can be measured across the whole integrated care process.

9. LOCATION OF PREMISES

9.1 Provision for MRI, Ultrasound, Cardiac, DEXA and X-ray services should be available in each of the 5 boroughs and within 1 mile of the neighbouring NCL borough(s) boundary.

9.2 Access to good transport links is also essential and must be taken into consideration when a provider establishes a service location. The NCL CCGs would not expect patients to have more than a 5-10 minute walk from the nearest public transport service, e.g. bus, rail, tube to the service location, and would expect access to local disabled parking.

9.3 The Provider and Commissioners will explore options to develop an extended range of community based diagnostics (e.g. ultrasound, cardiology diagnostics) informed by the strategic direction set out in the NHS Long Term Plan, to inform the development of services in the community and

primary care across at multiple borough locations across the five North Central London boroughs.

10. NEVER EVENTS

10.1 The Provider shall report Never Events as outlined in Table C and the prevailing NHS Standard Contract.

Table C: Never Events

Never Events	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
Misidentification of Patients	>0	Monthly and Quarterly performance report	In accordance with applicable guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care (not discretionary)

11. SERVICE USER EXPERIENCE AND PATIENT SAFETY

11.1 Service User Experience

11.1.1 All patients having the procedure should be asked to complete an anonymous pre and post procedure satisfaction survey. The completed surveys should be collated and put into a report and then forwarded to the contract manager on a quarterly basis so that they can be used to improve quality and further service development. The information gathered by the patient satisfaction survey should be taken into account when reviewing standards as part of clinical audit.

11.1.2 The Service Provider should put in place an effective Complaints Procedure and have systems in place to monitor the incidence and outcome of all complaints and investigations regarding the service. An aggregated complaints report should be provided to the Commissioners on a quarterly basis to show number and nature of complaints. Untoward incidents and near misses should be reported to the Commissioner immediately. All major complications should be audited together with deviations from planned care.

11.2 Patient Safety

11.2.1 The Provider will comply with policies and procedures on:

- Infection Prevention and Control
- Complaints and compliments
- Management and reporting of all incidents, including serious untoward incidences (SUIs) and near misses
- Never Events occurrences
- Risk assessment and risk management
- Information Governance
- Meeting the duties of equality legislation
- Safeguarding Adults
- Data protection
- Patient Advice and Liaison (PALS)
- Quality Assurance/ maintaining good practice
- Clinical and Professional Development (CPD), supervision and training

12. DATA/INFORMATION REPORTED FOR CONTRACT MONITORING

In complying with this section, the Providers attention is also drawn to Information Management Technology (IMT) requirements outlined in clause 4.16.

12.1 Data for data quality monitoring purposes as outlined in Table D.

Table D: Data Quality

Data Item	Expected level of coverage Non SUS data (diagnostics)	Expected level of coverage (SUS submissions)
DOB complete/valid	99%	99%
First attendance	100%	100%
Attended/DNA	98%	98%
NHS Number*	97%	97%
Referral source	97%	97%
Organisation code of referrer	98%	98%
Type of diagnostic test	99%	n/a

**If NHS number not given then patient name must be provided*

12.2 Data for contract monitoring purposes as outlined in Table E but local knowledge and experience should prevail.

Table E: Monitoring Information

Type of collection	Data Type	Essential / Desirable	Comments	Format/definition
Demographic	NHS Number	E	To enable linkage to other providers on pathway	10 digit NHS Number
Demographic	Patient Date of Birth	D	To validate NHS Number on Summary Care Record	Date format DD/MM/YYYY
Referral	Unique referral identifier	E	To monitor repeat activity, if another attendance offered then same referral identifier should be used in second and subsequent attendances	Format to be confirmed by diagnostic provider, but suggest numerical /integer
Referral	Organisation code of referrer	E	Practice Code	6 digit national GP practice code
Referral	Organisation code of commissioner	D	CCG Code	3 or 5 digit national code
Referral	Organisation code of provider	D	Provider Code	As per NHS Data Dictionary Coding Frames

Type of collection	Data Type	Essential / Desirable	Comments	Format/definition
Referral	Date sent by referrer	E	To monitor time on pathway	Date format DD/MM/YYYY
Referral	Date received by provider	E	To monitor time on pathway, system delays	Date format DD/MM/YYYY Date of referral is date the referral was received by the service
Referral	Date referral accepted by provider	E	To monitor time on pathway, system delays	Date format DD/MM/YYYY
Referral	Referral source	E	Taken from NHS Data Dictionary definition	Initiated by the CONSULTANT responsible for the Consultant Out-Patient Episode 01 following an emergency admission 02 following a Domiciliary Consultation 10 following an Accident and Emergency Attendance 11 other - initiated by the CONSULTANT responsible for the Consultant Out-Patient Episode Not initiated by the CONSULTANT responsible for the Consultant Out-Patient Episode 03 referral from a GENERAL MEDICAL PRACTITIONER 92 referral from a GENERAL DENTAL PRACTITIONER 2 referral from a General Practitioner with a Special Interest (GPwSI) or Dentist with a Special Interest (DwSI) 4 referral from an Accident and Emergency Department (including Minor Injuries Units and Walk In Centres) 05 referral from a CONSULTANT, other than in an Accident and Emergency Department 06 self-referral 07 referral from a Prosthetist 13 referral from a Specialist NURSE (Secondary Care) 14 referral from an Allied Health Professional 15 referral from an OPTOMETRIST 16 referral from an Orthoptist 17 referral from a National Screening Programme 93 referral from a Community Dental Service 97 other - not initiated by the CONSULTANT responsible for the Consultant Out-Patient Episode

Type of collection	Data Type	Essential / Desirable	Comments	Format/definition
Referral	Test requested	D	Reason for referral, to check referral compliance	Text field
Attendance	Unique activity identifier	E	To separate multiple tests on same day. This is not the same as the unique referral identifier	Format to be confirmed by diagnostic provider, but suggest numerical /integer
Attendance	Date and time of diagnostic test	E	To monitor time on pathway, contract activity reconciliation	Date format DD/MM/YYYY hh:mm
Attendance	Duration of attendance	E	To monitor contract activity	Numerical/integer Number of minutes
Attendance	First Attendance	E	To monitor contract delivery	1 First attendance face to face (First Diagnostic) Follow-up attendance face to face (Repeat Diagnostic) 3 First telephone or telemedicine consultation (N/A) 4 Follow-up telephone or telemedicine consultation (N/A)
Attendance	Type of diagnostic test	E	What diagnostic test / procedure did The Provider perform? To monitor contract delivery	OPCS4 codes or locally defined list?
Attendance	Anatomical site	D	To monitor contract delivery	Add the area of the body requiring diagnostic
Attendance	Staff type seeing patient	E	To monitor contract delivery	Lead Care Professional Member of Care Professional team
Attendance	Attend / DNA	E	To monitor contract delivery	5 Attended on time or, if late, before the relevant CARE PROFESSIONAL was ready to see the PATIENT 6 Arrived late, after the relevant CARE PROFESSIONAL was ready to see the PATIENT, but was seen 7 PATIENT arrived late and could not be seen 2 APPOINTMENT cancelled by, or on behalf of, the PATIENT 3 Did not attend - no advance warning given 4 APPOINTMENT cancelled or postponed by the Health Care Provider 0 Not applicable - APPOINTMENT occurs in the future *
Attendance	Seen By	E	To monitor contract delivery	Name of person completing
Outcome	Patient Outcome	E		1 Discharged from CONSULTANT's care (last attendance)

Type of collection	Data Type	Essential / Desirable	Comments	Format/definition
				2 Another APPOINTMENT given 3 APPOINTMENT to be made at a later date
Outcome	Date result reported	D	To monitor time on pathway, system delays	Date format DD/MM/YYYY
Outcome	Date result communicated to referrer	E	To monitor time on pathway	Date format DD/MM/YYYY
Contract	Currency type	E	Contract monitoring and reconciliation	PBR/nonPBR?
Contract	HRG	E	Contract monitoring and reconciliation	Refer to list of HRGs
Contract	Base HRG cost	D	Contract monitoring and reconciliation	Numerical/Decimal
Contract	Total cost of diagnostic test provided	E	Contract monitoring and reconciliation	Numerical/Decimal Zero cost for DNAs/Cancellations or repeat test for non-clinical reason

APPENDICES

APPENDIX A CLINICAL SPECIFICATION NON-OBSTETRIC ULTRASOUND

1. 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;

2. If the sonographer requires input from a Consultant Radiologist, this should be available within 24 hours of the investigation. This should be provided by a Radiologist with expertise and current involvement in Ultrasound.

3. The Provider shall submit detailed protocols governing sonographer performance of ultrasound procedures;

4. Evidence should be provided that these have been developed in concert with a radiologist expert in ultrasound and that there is a programme of constant review of the examination protocols;

5. Sonographers will be expected to undertake regular audit and revalidation in keeping with the policy of the SCoR

6. Clinical inclusions and exclusions specific to Ultrasound:

6.1 Inclusions: The following scans are included within service specification:

- General abdominal – includes assessment of the aorta, biliary tract, gallbladder, inferior vena cava, kidneys, liver, pancreas, retro-peritoneum and spleen;
- Gynaecology – including transabdominal and transvaginal;
- Renal / bladder / prostate;
- Scrotal / testicular;
- Musculoskeletal; and
- Vascular
- Superficial masses or lumps in the neck or groin (where a biopsy is not needed)
- Other lumps and bumps

6.2 Exclusions: The following scans are excluded from this service specification:

- Breast
- Cardiac imaging
- Ophthalmology
- Superficial masses or lumps in the axilla
- Obstetric care
- Ultrasound guided procedures
- Thyroid
- Chest

7 Standards and Guidance:

7.1 The Provider shall comply with Medicines & Healthcare products Regulatory Agency (MHRA) Ultrasound Equipment Evaluation Project (UEEP) recommendations as published from time to time.

8 Equipment

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

8.1.1 Compliance with the latest 'Standards for Ultrasound Equipment', Royal College of Radiologists;

8.1.2 Transducers that ensure good visualisation at sufficient depth of image without significant loss of accurate spatial resolution; and

8.1.3 Capability of flow imaging and measurement.

9 Staff

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

9.1.1. UK Registered Radiologists and / or APCP Radiographers on the GMC Specialist Register who have:

- Reported on a minimum of 500 ultrasound scans in the last 12 months; and
- Achieved a Significant Reporting Error rate of <0.1% measured over the preceding 12 month period or such shorter period as the Authority shall in its absolute discretion determine upon application for such determination by The Provider.

9.1.2 APCP Radiographers

9.1.3 Ultrasonographers Deemed Competent and registered with the appropriate registering body who:

- Have performed a minimum of 500 USS in the last 12 months
- Meet the specification set out in the National Occupational Standards for Imaging:
  - RD3A - abdomen & pelvis;
  - RD3B - transabdominal gynaecology;
  - RD3E- vascular; and/or
- Have successfully completed an appropriate Consortium for the Accreditation of Sonographic Education (CASE) course and have maintained their Continuing Professional Development in accordance with professional guidelines; or

9.1.4 UK Registered Doctors who are not on the GMC Specialist Register (who must be Deemed Competent) who:

- Have undergone appropriate certification of competency as agreed with the Authority;
- Have performed a minimum of 500 USS in the last 12 months; and
- Meet the specification set out in the National Occupational Standards for
- Imaging:
  - RD3A - Abdomen & pelvis;
  - RD3B - Transabdominal Gynaecology; and
  - RD3E- vascular.

9.2 In respect of the first 50 ultrasound scans conducted by each individual ultrasonographer referred to in paragraph 9.1.2 above, such ultrasonographer shall be supervised by a radiologist present at the scan and working alongside the relevant ultrasonographer.

10 Case Mix

10.1 The Provider shall provide the following Korner categories:

- All bands in B3 (but excluding exam code U31 paediatric kidney);
- All band C2 (but excluding exam code U35 U/S drainage); and
- All band D3 (but excluding code UG9 obstetric Doppler).

10.2 The case mix shall include but is not limited to:

- Abdomen: includes assessment of the liver, gallbladder, biliary tract,
- Pancreas, spleen, kidneys, aorta, inferior vena cava and retroperitoneum;
- Female pelvis, transvaginal and trans abdominal;
- Bladder;
- Scrotum/testicular; and
- Vascular ultrasound:
- Peripheral veins;
- Carotid duplex ultrasound;

11 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).
- Refer Making the Best Use of a Clinical Radiology - Royal College of Radiologists (2012).
- 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).

12 Applicable Quality Requirements

12.1 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, working in isolation is not and this must be addressed by Providers. This is an important governance issue and is addressed in the document "Team Working in Clinical Imaging" jointly produced by the Royal College of Radiologists and the Society and College of Radiographers 2012.

http://www.rcr.ac.uk/publications.aspx?PageID=310&PublicationID=373

12.2 The proposed Quality Assurance process should include, as a minimum:

- On-going 5% audit of ultrasound examinations to include the technical quality of the examination, the quality of static images captured, and the structure and content of clinical reports; with trigger values set for detailed review of service/performance mechanisms to be agreed with Commissioner;
- Annual assurance of competency and up to date continuous professional development
- Participation by all clinical staff in 'local errors meetings' or similar clinical governance process.
- The recall rates for patients (annual report) and reasons.

12.3 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.

13 The ultrasound team must be comprising of a network radiologists, registered ultrasonographers and, who must work together to deliver a high standard of clinical care.

14 The clinical team must be supported by an experienced administration team that ensures the service is patient focused, efficiently delivered with minimal patient DNA's (Did Not Attend) as well as robust GP communication to deliver excellent service to patients.

APPENDIX B CLINICAL SPECIFICATION MAGNETIC RESONANCE IMAGINING SERVICE

1. Clinical Exclusions

1.1 Patients with implanted medical devices that are MRI contraindicated and in certain cases are MRI conditional. The referrer has a responsibility to provide information on all such devices, but the final responsibility for safety rests with the Provider in line with Provider protocols and relevant safety guidelines and resources.

2. Other exclusions

- Patients requiring a general anaesthetic
- Scans requiring contrast
- NHS Patients with severe claustrophobia
- NHS Patients weighing in excess of the maximum weight rating for the MR scanner being used
- For the avoidance of doubt, NHS Patients with suspected infraorbital foreign bodies should receive a 'hot reported x-ray' there and then whenever possible, to avoid cancellation.

3. Equipment

3.1 The Provider shall provide equipment that meets or exceeds the following specification: ≥1.5 Tesla MR scanner(s).

4. Staff

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

4.1.1 UK Registered Radiologists on the GMC Specialist Register who have:

- Reported on a minimum of 500 MR scans in the last 12 months;
- Achieved a Significant Reporting Error rate of <0.1% or such shorter period as the Authority shall in its absolute discretion determine upon application for such determination by The Provider;

4.1.2 UK Registered Radiographers who meet the specification set out in the National Occupational Standards for Imaging (RD5- Produce MR images for diagnostic purposes);

4.1.3 UK Registered Clinical Scientists, or personnel acting under the supervision of a UK Registered Clinical Scientist, to undertake medical physics duties e.g. quality assurance, and equipment acceptance testing.

5. Casemix

5.1 The Provider shall provide the following casemix:

- MRI, one area, no contrast
- MRI, 2-3 areas, no contrast
- MRI, more than 3 areas, no contrast

5.2 The Provider shall provide all band F1 Korner categories, including without limitation listed below:

- Brain;
- Spine: cervical, thoracic, lumbar;
- Head and neck;
- Musculoskeletal system including: wrist, shoulder, hips, knee, ankle, SIJ, soft tissue.

6. Report

6.1 The Provider shall ensure:

6.1.1 That the Diagnostic Report is produced according to the "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 format agreed with the Authority;

6.1.2 That the Diagnostic Report is always authenticated by a radiologist on the UK GMC specialist register, who meets the requirements in paragraph 3.1(a) of this specification; and

6.1.3 For specialist scans the Reporting Clinician has produced the minimum number of MR Diagnostic Reports for the relevant anatomical area in accordance with the table below:

Subspecialty	**Minimum number of diagnostic reports produced in the last year for the required anatomical area by the Reporting Clinician**
Neurology	250
Head and neck	150
Musculoskeletal	500
Chest	150

6.2 The parties shall review the figures in the above table at the commencement of each Contract Year to take into account Activity volumes and Good Clinical Practice.

6.3 The Provider shall ensure that for Referrals for complex neurology MR scans (i.e. Referrals from tertiary NHS centres), the Diagnostic Report shall be authenticated by a neuro-radiologist of at least equivalent reporting skill as an NHS tertiary centre neuro-radiologist.

APPENDIX C CLINICAL SPECIFICATION X-RAY

1. The Provider will supply and install the X-Ray to the separate technical specification, storage system and required connectivity with services. (N/A – equipment already in situ).

2. STAFF

2.1 The Provider shall ensure that the service is delivered by Staff meeting the following standards:

2.1.1 UK Registered Radiologists on the GMC Specialist Register who have:
- Reported on a minimum of 2000 x-rays in the last 12 months; and
- Achieved a Significant Reporting Error rate of <0.1% measured over the preceding 12 month period or such shorter period as the Authority shall in its absolute discretion determine upon application for such determination by The Provider;

2.1.2 UK Registered Radiographers who:
- Have competently performed a minimum of 2000 x-rays in the last 12 months; and
- Meet the specification set out in the National Occupational Standards for X-ray:
  - RD.1A Produce plain radiographic images of the appendicular skeleton for diagnostic purposes;
  - RD.1B Produce plain radiographic images of the chest & thorax for diagnostic purposes;
  - RD.1C Produce plain radiographic images of the spine and pelvis for diagnostic purposes;
  - RD.1D Produce plain radiographic images of the abdomen for diagnostic purposes;
  - RD.1E Produce plain radiographic images of the skull for diagnostic purposes;
  - RD.8A Interpret and report on plain radiographic images of the appendicular skeleton;
  - RD.8B Interpret and report on plain radiographic images of the axial skeleton;
  - RD.8C Interpret and report on plain radiographic images of the chest;
  - RD.8D Interpret and report on plain radiographic images of the abdomen;

2.1.3 UK Registered Clinical Scientists, or personnel acting under the supervision of a UK Registered Clinical Scientist, to undertake medical physics duties (e.g. quality assurance, and equipment acceptance testing).

3. CASEMIX

3.1 The Provider shall provide the following casemix:
- Conventional x-ray imaging (Plain Film), one area
- Conventional x-ray imaging (Plain Film), two or three areas

3.2 The Provider shall provide the following Korner categories:
- Band A (excluding theatre x-rays); and

- Band B4 (excluding theatre x-rays, contrast studies, or fluoroscopy).

3.3 The casemix shall include:

- Skull, facial bones, sinuses, orbits, nasal bones where recommended by RCR guidelines;
- Spine – cervical, thoracic, lumbar sacral unless MRI is indicated by clinical information, sacrum;
- Pelvis, hips;
- Shoulder - clavicle, scapulae, acromio-clavicular joints;
- Thorax – chest, , sternum (including articulating joints);
- Abdomen – KUB;
- Femora, knees, ankles, feet, tarsal & metatarsals; and
- Humeri, elbows, wrists, hands, carpals, metacarpals.

4. ACQUISITION PROTOCOL

4.1 The Provider shall ensure that NHS Patients are x-rayed according to evidence based scanning protocols that optimise the diagnostic utility of the Investigation Output.

5. REPORT

5.1 The Provider shall ensure:

5.1.1 That the Diagnostic Report is produced according to the “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 format agreed with the Authority; and

5.1.2 That the Diagnostic Report is always authenticated by a physician on the UK GMC specialist register or a radiographer who has been Deemed Competent to report.

APPENDIX D CLINICAL SPECIFICATION CARDIOLOGY DIAGNOSTIC SERVICES

1. 12 Lead ECG

1.1 A 12 lead ECG specification will be jointly agreed within the first month following implementation of the new contract, consistent with the specification previously used in the London Diagnostics Service and in effect from 7 April 2007 to 30 April 2014 (the 'LDS Service') unless otherwise agreed. Reports will be provided to referrers following established LDS Service reporting methodology.

2. Ambulatory ECG

2.1 Outline of the Service

2.1.1 Equipment:

2.1.1.1 Appropriate recording devices (e.g. 24 hours, 48 hours and 7 day event), conforming to standards specified by the IQIPS (http://www.rcplondon.ac.uk/projects/IQIPS) will be provided by The Provider. These devices will be provided appropriately calibrated, in working order and will be maintained according to manufacturer's specification. They will be kept at clusters of sites and fitted locally.

2.1.1.2 Patients meeting the criteria for this test (see management pathway) will be referred by the requesting GP and will be invited to attend a local base for fitting the device. Instructions on its use and return will be provided.

2.1.1.3 Once patients have completed the monitoring period (24 hours, 48 hours, 7 day event) they will be asked to return to the local base and have the device removed so that information can be digitally transferred for appropriate clinical interpretation and record storage.

2.1.1.4 This clinical interpretation will be made by either a Cardiac Physiologist or another appropriately trained professional within a period that will enable the registered GP to get a report within 2 days of the device being returned.

2.1.1.5 The registered GP will use the interpretation to decide how to manage the patient from there on e.g. further diagnostic tests and / or discuss treatment options.

2.1.2 Clinical Management Pathway

2.1.2.1 Stage 1 – The consultation

- It is up to the GP to determine whether the patient has a level of risk which requires specialist assessment.

- Patients will be included in this diagnostic pathway (a subset of the overall cardiac pathway) by their GP if they report symptoms of:
  - Palpitations,
  - Irregularity,
  - Feelings of dizziness,

- Light headedness,
- “Fainting or falls” (note these patients require a careful assessment of risk of significant problems warranting urgent specialist assessment).

- Patients experiencing palpitations less frequently than daily should be considered for loop event recorder investigation (7 day event recorder).

- The GP should take a history and perform any necessary examination. If this reveals any high risk factors (see below) then there should be a referral to an appropriate specialist service. Patients who at clinical interview or examination have severe symptoms or have high risk (e.g. FHx, sudden death under 40 years) should be excluded from this pathway and be referred to a specialist service. Other symptoms which raise clinical concern should be discussed with an appropriate clinician to decide if an ambulatory ECG would be helpful or not. Before referral to an ambulatory ECG service, a resting 12-lead ECG (or point of care ECG) and appropriate blood tests should be carried (this is not a pre-requisite).

- Patients with significant abnormalities detected in the 12-lead ECG should be referred to secondary care. Where this level of concern is not identified and where the clinician feels that an ambulatory ECG would help in the diagnosis and management of the patient the cardiac physiology procedure for testing should be used.

2.1.2.2 Low Risk group

- Patients who fulfil the following criteria should initially be treated conservatively:
  - No history of sustained tachycardia or loss of consciousness AND
  - Good exercise capacity AND
  - No family history of Sudden Cardiac Death < 40 years AND
  - Normal cardiac examination AND
  - Normal 12 lead ECG

2.1.2.3 Clinical Exclusions

- High Risk Patients/High Risk Factors
  - Patients with symptomatic ectopics accompanied by significant chest pain or shortness of breath or
  - syncope and pre-existing cardiac disease (prior MI, CABG, adult congenital heart disease (ACHD)
  - Significant congestive heart failure should be referred to a general cardiology clinic
  - Patients with no prior cardiac history and an abnormal resting ECG (apart from 1st degree heart block or RBBB) should be referred to a general cardiology clinic
  - Patients with a personal history of loss of consciousness or a family history of sudden death < 40 years should be referred to a heart rhythm specialist
  - Patient with a suspected drug related phenomenon (e.g. acquired long QT syndrome) should be referred to a heart rhythm specialist

2.1.2.4 Applicable national standards, e.g. NICE, Royal College

- Services should meet standards expressed in the IQIPS (http://www.rcplondon.ac.uk/projects/IQIPS).

- Accreditation to those standards will take place from 2014 (1st quarter) and all providers are strongly encouraged to accredit their services. Working towards and completing accreditation will give cost efficiency benefits. The services are presented as 3 distinct areas of work;
  - Fitting the device to the patient
  - Collecting the reading and sending onwards for analysis and interpretation
  - Interpretation and return.

- For each of these 3 areas of work staff should have appropriate levels of training and education.

- The regular returns for the commissioner should detail performance on the local commissioning targets in the contract for each of the three areas used first.

2.1.2.5 Acquisition Protocol

- The Provider shall:
  - Check the NHS Patient's medication history for use of cardiac drugs and note the use of such drugs on the report;
  - Note on the tracing if the NHS Patient has any cardiac symptoms (e.g. chest pain or palpitations) at the time of recording.

2.1.2.6 Report

- The Provider shall provide:
  - The Investigation Output; and
  - If required a Diagnostic Report, which shall:
    - Be in the format agreed with the Authority;
    - Be authenticated by a physician who meets the requirements and they are Deemed Competent; and
    - Use ECG terminology consistent with The Society for Cardiological Science and Technology or ACC/AHA practice guidelines.

3. Echocardiography

3.1 Equipment

3.1.1 The equipment shall meet or exceed the following minimum specifications:

- High diagnostic utility imaging capability, featuring high resolution and grey scale and including the availability to do harmonic imaging;
- Full Doppler capability, including pulsed wave, continuous wave, colour and tissue Doppler;
- Colour flow imaging;
- Be configured specifically to cardiac application;

- Be equipped with probes capable of 2-6 MHz frequencies for adults. In addition, the equipment will include a continuous wave Doppler capability;
- Ability to perform on screen measurements of distance, time, velocity and derived calculations such as volumes, pressure gradients, valve areas and blood flow; and
- Be available for either videotape or digital or hard copy recording of studies.

3.1.2 The Provider shall provide full transthoracic echocardiograms.

3.2 Staff

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

- Physicians on the GMC Specialist Register and GPs with specialist interest who have competently performed and accurately reported on at least 300 transthoracic echocardiograms in the past year;
- Cardiac physiologists who:
  - Are statutory registered with the HPC; or
  - Are voluntary registered with The Registration Council of Clinical Physiologists for Cardiological Science and Technology and are Deemed Competent; and
  - Have proficiency in echocardiography defined by British Society of Echocardiography affiliated to the British Cardiac Society and the Society for Cardiological Science and Technology and are Deemed Competent; and
  - Are Deemed Competent to the assessment standards of the British Society of Echocardiography (BSE); BSE accreditation is desirable;
- Certified cardiac sonographers who are Deemed Competent and:
  - Have competently performed at least 300 studies in the past year;
  - Are able to obtain pertinent clinical information from the patient, referring physician, and patient's record, including cardiac related physical findings and pertinent laboratory data;
  - Can apply the necessary sonographic techniques to obtain comprehensive and diagnostic echocardiographic information; and
  - Are able to obtain and integrate such data to avoid incomplete examination, erroneous clinical interpretation of the echocardiogram, or both.

3.3 Excluded Patients

3.3.1 The Provider shall not be required to carry out the Activity on NHS Patients who meet the exclusion criteria set out in Section 3.4.2 and 5.2 of the Service Specification.

3.4 Acquisition Protocol

3.4.1 The Provider shall comply with procedures that optimise the diagnostic utility of the Investigation Output.

3.5 Report

3.5.1 The Provider shall:

- Ensure that the Diagnostic Report is always authenticated by either a physician on the UK GMC specialist register, who meets the requirements in paragraph 3.1(a) of this specification or a clinician meeting the requirements of either paragraphs 3.1(b) or 3.1(c) of this specification who has been Deemed Competent;
- Comply with guidance of the British Society of Echocardiography Education Committee "Minimum dataset for adult Transthoracic echocardiography" and is in the format agreed with the Authority; and
- Specify whether the patient has heart failure (Yes/No) if relevant to the Referral.

4. Ambulatory Blood Pressure Monitoring

4.1 Standards and Guidance

4.1.1 The Provider shall comply with the latest standards and guidance of The British Hypertension Society and The European Society of Hypertension.

4.2 Equipment

4.2.1 The Provider shall provide ambulatory blood pressure measuring device(s), approved by the MHRA.

4.3 Staff

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

- UK GMC registered physicians who have accurately reported on at least 25, ambulatory blood pressure cases in the past year, and 50 in the previous year;
- Health Care Scientists, cardiac physiologists and other healthcare professionals who:
  - Are statutory registered with the HPC; or
  - Are voluntary registered with The Registration Council of Clinical Physiologists for Cardiological Science and Technology; and
  - Have performed at least 100, 24 hour ambulatory blood pressure tests in the past year; and
  - Have competencies defined by The Society for Cardiological Science and Technology (A.S.C.S.T); and
- Health Care Assistants who are Deemed Competent.

4.4 Excluded Patients

4.4.1 The Provider shall not be required to carry out the Activity on NHS Patients who meet the exclusion criteria set out in Section 3.4.2 and 5.2 of the Service Specification.

4.5 Acquisition Protocol

4.5.1 The Provider shall comply with procedures that optimise the diagnostic utility of the Investigation Output.

4.6 Report

4.6.1 The Provider shall provide:

- The Investigation Output including:
  - Mean daytime systolic and diastolic pressures and heart rate;
  - Mean night-time systolic and diastolic pressures and heart rate;
  - Mean 24 hour systolic and diastolic pressures and heart rate; and
- If required a Diagnostic Report, which shall:
  - Be in the format agreed with the Authority;
  - Be authenticated by a physician who meets the requirements in paragraph 3.1(a) of this specification;
  - Include the requirements of paragraphs 14 of Part 2 of this Schedule 3;
  - State whether the patient has hypertension or white coat hypertension; and
  - State whether the patient warrants antihypertensive drug treatment or manipulation of current antihypertensive drug treatment, in accordance with National Institute for Health and Clinical Excellence guidance.

APPENDIX E CLINICAL SPECIFICATION DUAL ENERGEY X-RAY ABSORPTIOMETRY (DEXA) SCANNING

1. Introduction

1.1 DEXA is 'dual energy X-ray absorptiometry' and is a test that measures the density of bones. Central DEXA devices are large machines that can measure bone density in the centre of your skeleton, such as your hip and spine. Reports will be provided to referrers following established Service reporting methodology.

1.2 A DEXA scan may be advised for those at increased risk of osteoporosis. Therefore, a DEXA scan may be advised in the following instances:

- A fracture following a minor fall or injury.
- Loss of height due to fracture of a vertebra (back bone).
- Taken steroid tablets for three months or more.
- An early menopause (aged less than 45).
- A history of periods stopping (amenorrhea) for more than one year before the menopause.
- Other disorders associated with osteoporosis such as rheumatoid arthritis or coeliac disease.
- A family history of hip fracture on maternal side
- A body mass index of less than 19.

2. The Facilities

2.1 The Facilities providing DEXA will meet the requirements stated within the contract.

3. Statement of intent for the facilities (DEXA Clinical Specification)

3.1 Facilities

3.1.1. Dual-energy x-ray absorptiometry equipment will be available

3.1.2 Staff

3.1.2.1 The diagnostic DEXA service shall be provided by the following staff:

- UK Registered Radiographers or practitioners who have successfully completed an appropriate training course, and can demonstrate clinical competence. The training should include underpinning theoretical knowledge, as well as a skills based assessment.

3.1.3 Anatomical Sites

- Standard central / axial DEXA examination of AP spine and proximal femur scans
- Anatomic areas of known prior fracture or prior surgery will be excluded from measurement.

3.1.4 Contra Indications to DEXA

3.1.4.1 Patients with the following characteristics will be excluded:

- Recent barium (for spine measurements) or radionuclide studies

- Severe arthritic or fracture deformity or other degenerative changes at the site to be measured
- Radio-opaque implants in the measurement area, most commonly at the hip
- A patient's inability to maintain correct position and/or remain motionless for the duration of the measurement

3.1.5 Referral Clinical Data

3.1.5.1 Patients will be accepted for scanning who are referred in accordance with the Royal College of Radiologists Referral Guidelines. The referrer shall include the following information:

- Predisposing factors for osteoporosis
- Prior fragility fractures
- Prior bone trauma/fractures or surgery
- Drug medication e.g. long-term therapy with glucocorticoids, thyroid replacement, or other medications (such as phenytoin or heparin)

3.1.6 Patient Questionnaire

3.1.6.1 Patients will complete a questionnaire prior to their appointment at the unit before they are scanned.

3.1.7 Report

3.1.7.1 The report will be issued in accordance with local protocols. The report shall be provided to the referring clinician within 48 hours of the test, the patient will be issued with a copy at the time of the scan.

3.1.7.2 Reports shall include for each site examined:

- Bone mineral density
- T-score / Z-score
- Corresponding percentages of mean
- Fracture risk
- Comparison with previous studies, if available
- Patients classified according to World Health Organization criteria
- A statement of whether a change in BMD is significant, where serial examinations are reviewed

3.1.7.3 The aim of the Facility providing DEXA is to provide a safe, welcoming environment for diagnostic investigation by DEXA of patients deemed to be suitable for the procedure. This service will be provided on behalf of the patient's GP who will maintain clinical responsibility for their patients.

APPENDIX F MODALITIES

A. NCL CCG GP DIRECT ACCESS DIAGNOSTIC IMAGING Contract element

For clarification purposes, NCL CCGs intends only to commission/purchase the following modalities under this Service Specification, to support delivery of the NCL CCGs GP Direct Access Diagnostic Imaging contract:

Clinical Commissioning Group				
Barnet	**Camden**	**Enfield**	**Haringey**	**Islington**
MRI	MRI – Non MSK	MRI	MRI	MRI
Ultrasound	Ultrasound	Ultrasound	Ultrasound	Ultrasound
X-ray imaging	X-ray imaging	X-ray imaging	X-ray imaging	X-ray imaging
DEXA scan		DEXA scan	DEXA scan	DEXA scan
Ambulatory ECG	Ambulatory ECG	Ambulatory ECG	Ambulatory ECG	Ambulatory ECG
Blood Pressure Monitoring	Blood Pressure Monitoring	Blood Pressure Monitoring	Blood Pressure Monitoring	Blood Pressure Monitoring
ECG (24hours, 48 hours, 7 day event recorder)	ECG (24hours, 48 hours, 7 day event recorder)	ECG (24hours, 48 hours, 7 day event recorder)	ECG (24hours, 48 hours, 7 day event recorder)	ECG (24hours, 48 hours, 7 day event recorder)
Echocardiogram	Echocardiogram	Echocardiogram	Echocardiogram	Echocardiogram

B. UCLH / Camden CCG MSK Contract element:

For clarification purposes, UCLH intends only to commission/purchase the following modalities under this Service Specification, to support delivery of the UCLH/Camden CCG MSK contract:

Modalities	**To note/Follow up actions required**
MRI	• Parties will need to set up individual requesting protocols between Camden MSK clinician's (and other NCL non-medical providers if desired) and the Provider detailing the requesting privileges based on the clinician's competency rather than by the existing strategy of body part
X-ray imaging	• Parties will need to set up individual protocols between Camden MSK clinicians and the Provider for relevant requesting rights for MSK X-ray • Parties will establish a governance structure to measure compliance against the agreed protocol • This framework will provide an education structure for clinicians & staff
Ultrasound	• Parties will need to set up individual protocols between Camden MSK clinicians and the Provider for relevant requesting rights for MSK Ultrasounds • Parties will establish a governance structure to measure compliance against the agreed protocol • This framework will provide an education structure for clinicians & staff
DEXA scan	• Parties will need to set up individual protocols between Camden MSK clinicians and the Provider for relevant requesting rights for MSK DEXA Scans • Parties will establish a governance structure to measure compliance against the agreed protocol • This framework will provide an education structure for clinicians & staff

APPENDIX G REQUIRED REPORT FORMAT/TEMPLATE

Usual GP Full Name
Usual GP Organisation Name
Usual GP Full Address (stacked)

REPORT: GP DIRECT ACCESS DIAGNOSTIC IMAGING SERVICE

Dear Usual GP Title Usual GP Surname,

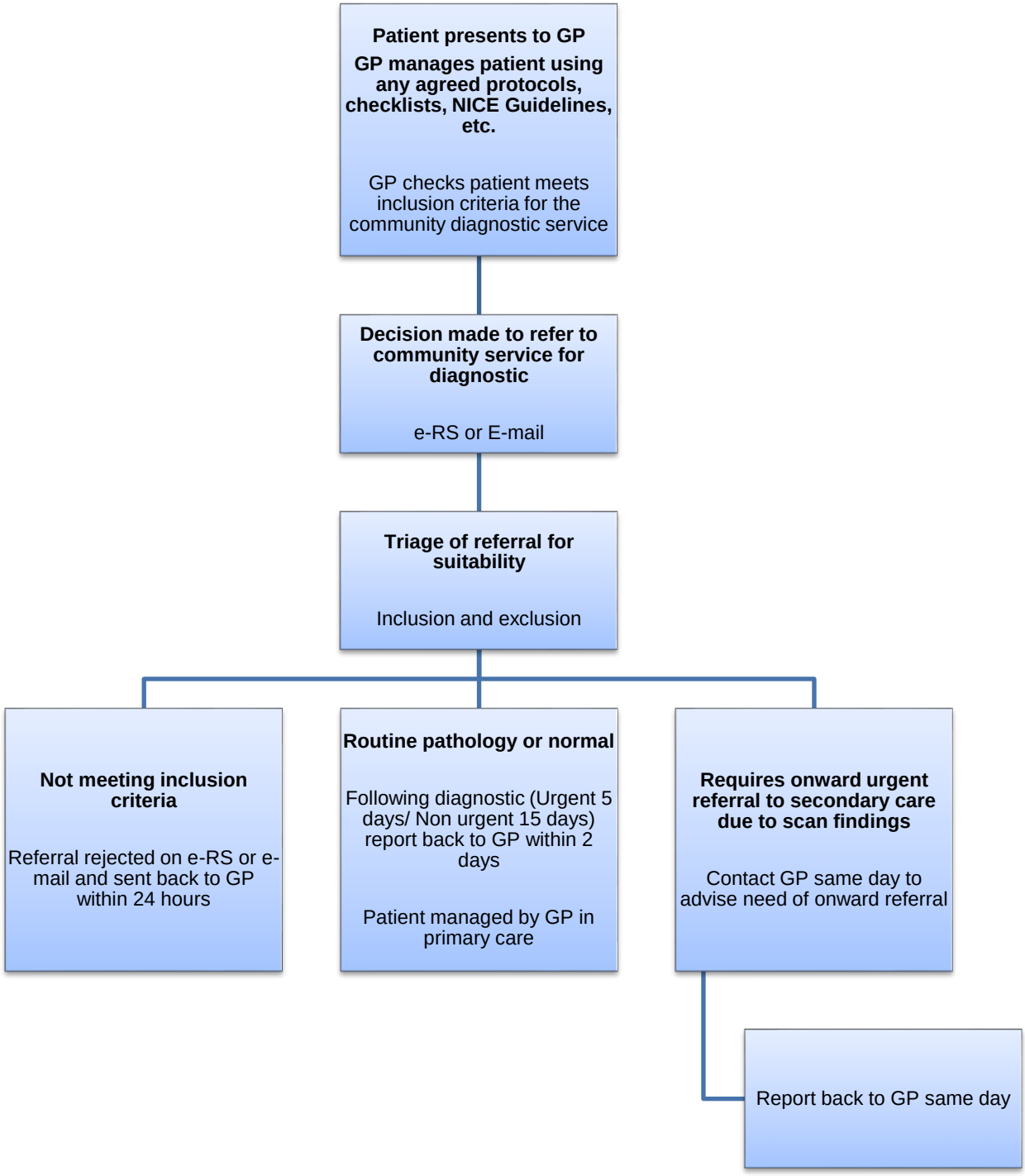
Patient Name: Title Given Name Surname **D.O.B:** Date of Birth **Sex:** Male/Female **NHS No:** NHS Number **Address:** Home Full Address (single line)
Previous imaging: Yes/No **Location:**

Recommended Action:

Imagining service	E.g. X-ray, MRI, Echocardiogram, ECG, Ultrasound, DEXA
Name of Study	E.g. Plain radiograph left knee etc.
Date of the Study	
Reported By	Name: Title: Qualifications: Tel: Email:
Clinical Indication	
Report	
Recommendation for further investigation/specialist referral	Yes/ No/Clinical Correlation
Additional Information	
Codeable Diagnosis (SnowMed)	
Interpretation Summary	
Serious Unexpected Findings	Yes/No

cc. Title Given Name Surname
Home Full Address (stacked)

APPENDIX H COMMUNITY PATIENT PATHWAY FLOWCHART



APPENDIX I ABBREVIATIONS

ALS	Advanced Life Support
ACLS	Advanced Cardiac Life Support
CCG	Clinical Commissioning Group.
CDS	Commissioning Data Set
CQC	Care Quality Commission
CfH	Connecting for Health.
CNST	Clinical Negligence Scheme for Trusts
CPA	Care Programme Approach
DH	Department of Health.
DNA	Did Not Attend
GMC	General Medical Council
HRG	Healthcare Resource Groups
HSCIC	Health and Social Care Information Centre
IEP	Image Exchange Portal
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations
LINk	Local Involvement Networks e.g. Healthwatch These are made up of individuals and community groups, such as faith groups and residents' associations, working together to improve health and social care services.
MHRA	Medicines and Healthcare products Regulatory Agency
NCL	North Central London
NHS	National Health Service
NICE	National Institute of Clinical Excellence, an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.
NMS	National Minimum Standards
NSTS	NHS Strategic Tracing Service
PACS	Picture Archiving and Communications System
SCoR	Society of Radiographers
SMS	Short Message Service
SUS	Secondary Users System