

A03/S/a

**2013/14 NHS STANDARD CONTRACT
FOR SPECIALISED ENDOCRINOLOGY SERVICES (ADULT)**

PARTICULARS, SCHEDULE 2- THE SERVICES, A- SERVICE SPECIFICATIONS

Service Specification No.	A03/S/a
Service	Specialised Endocrinology Services (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

National Context

Adult specialist endocrine services are provided in a small number of dedicated units that have highly skilled staff and integrated services for patients with complex endocrine diseases. Delivery of adult specialist endocrinology services requires dedicated multi-professional teams with great experience in managing patients with multisystem, complex needs who often require specialist laboratory-based testing, imaging combined with medical and surgical management.

Please note: Paediatric endocrinology services are not detailed in this specification – please see separate paediatric endocrinology service specification.

Incidence rate

- Pituitary and hypothalamic disease is 10 per 10,000 population;
- Differentiated thyroid cancer is 4 per 100,000 population, medullary thyroid cancer is 0.5 per 100,000 population;
- Primary hyperparathyroidism incidence rate is 30 per 100,000 population;
- Adrenal disease: adrenocortical carcinoma is one per million population; pheochromocytoma is 2-8 per million population; adrenal adenoma causing Cushing's Syndrome is one per million population;
- Neuro-endocrine tumours: Carcinoid syndrome is 1 and gastrointestinal pancreatic neuroendocrine tumours is three per 100,000 population;

- Reproductive and gonadal endocrinology (disorders of sexual development) is 50 per 100,000 population;
- Complex calcium handling and metabolic bone diseases is ~ 5 per 100,000 per population;
- Familial Endocrine Disorders - Multiple endocrine neoplasia Type 1, Type 2 a or b rate of 1-3 per 100,000, Von Hippel Lindau disease rate of 3 and Neurofibromatosis rate of 30 per 100,000 population.

Evidence base

This specification draws its evidence and rationale from a range of documents and reviews as listed below:

- NICE quality standards for the management of growth hormone
- Royal College of Physicians guidelines
- Royal College Physicians management of thyroid conditions
- European guidelines for the management of endocrine condition
- Guidelines for the management of adrenal disease
- National guidelines for neuroendocrine tumours
- Consensus statement for acromegaly and other pituitary tumours, Wass / Clayton RCP
- Guidelines for the management of thyroid cancer, British Thyroid Association & Royal College of Physicians 2007
- Guidelines for the Management of Asymptomatic Primary Hyperparathyroidism: Summary Statement from the Third International Conference – Journal of Clinical Endocrinology and Metabolism, 2009 Feb; 94(2), 335-9

Consensus statement on the diagnosis, treatment and follow-up of patients with primary adrenal insufficiency, which has been accepted for publication in the Journal of Internal Medicine. ES Husebye^{1,2}, K Løvås^{1,2}, B Allolio³, W Arlt⁴, KBadenhoop⁵, S Bensing⁶, C Betterle⁷, A Falorni⁸, EH Gan⁹, A-L Hulting⁶, A Kasperlik-Zaluska¹⁰, O Kämpe¹¹, G Meyer⁵, SH Pearce⁹

UK guidelines for management of Addison's disease (primary adrenal insufficiency) that are available on http://www.cks.nhs.uk/addisons_disease

- European Neuroendocrine Tumour Network (ENET): Guidelines for neuroendocrine tumours (NETs)
- Paediatric Endocrine Tumours: a multidisciplinary consensus statement (British Society of Paediatric Endocrinology & Diabetes (BSPED) and UK Children's Cancer Study Group (UKCCSG) 2005
- Clinical practice guidelines for multiple endocrine neoplasia type 1, Journal of Clinical Endocrinology & Metabolism , June 2012
- MEN – Medullary thyroid cancer management guidelines of the American Thyroid Association 2009
- JCEM papers with guidelines Journal of Clinical Endocrinology and Metabolism 2012 e pub, Journal of Clinical Endocrinology and Metabolism 2001

- American Thyroid Association guidelines on medullary thyroid cancer 2009
- Improving outcomes for people with brain and other CNS tumours
- Improving outcomes for people with head & neck tumours
- NICE clinical guidelines: Improving outcomes in children and young people with cancer
- Manual for Cancer Services. Quality Measures 2011
- Society for Endocrinology: Specialist adult endocrinology services, Miles Levy 2011
- UK guidance for initial approach to infants and adolescents with suspected Disorder of Sex Development (put in full) (Clinical Endocrinology 2011)
- Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: an Endocrine Society clinical practice guideline. JCEM, 2010
- Consensus statement on management of intersex disorders. Archives of Disease in Childhood, 2006
- Consensus statement on the management of the GH-treated adolescent in the transition to adult care. European Journal of Endocrinology 2005
- CAP accredited genetic testing compliant laboratories; testing to UKGT standards.
- National Institute for Health and Clinical Excellence (NICE) Technology Appraisal (TA)161 Osteoporosis –secondary prevention including strontium ranelate
- Holistic management of DSD Brain et al 2010
- Consensus statement on management of intersex disorders Lee et al 2006
- Congenital Adrenal Hyperplasia due to 21-hydroxylase deficiency; an Endocrine Society clinical practice guideline, Speiser et al JEM 2010

Waiting times

All endocrine referrals are to be managed within 18 weeks, except for patients with actual or suspected endocrine malignancy which are reported under the Cancer Waiting Times – achievement of two week wait, 31 day wait to first treatment, 31 day wait to subsequent treatment, 62 day wait from referral to first treatment.

2. Scope

2.1 Aims and objectives of service

The aim of the service is to provide patient centred specialist care for adolescent (new referrals of young people 16+) and adults with agreed endocrine disease (as set out in section 2.2 below) and promote their optimal future and quality of life. Adolescent patients who are >16 and who have been previously been treated in the paediatric service can continue to access the paediatric service for their follow up for their condition if it requires ongoing endocrine input until full transition around 18-20 years.

The main diagnostic and monitoring methods include cytology, histology, radiological investigations, ultra sound (US), bone densitometry, computerized tomography (CT)/magnetic resonance imaging (MR) (including radiologically guided biopsy), functional nuclear medicine scans, endoscopic ultrasound, inferior petrosal sinus and adrenal venous sampling.

Treatments offered include medical, surgical and/or interventional radiological management of endocrine disease for adolescents (and their families) and adults. In addition the service will offer education, nutritional, psychological support and counselling about endocrine disease and treatment.

Medical treatment is predominately delivered in an outpatient setting, endocrine surgery requires in patient stay (most often 24 hour or more) and where appropriate in an inpatient (ward) or day unit based or on paediatric intensive care unit (PICU) if required, with carefully monitored shared care arrangements in place with referring clinicians.

The longer term strategic aim is for the national service to consider the service model where all thyroid surgery is centralized

The broad objectives of the service are to facilitate:

Diagnosis objectives:

Early identification of patients with complex multisystem disease, ensuring that they have timely access to specialist care for accurate diagnosis.

Rapid access for new and existing patients in an emergency against best practice clinical protocols.

Increase awareness of best practice in the diagnosis and management of these rare conditions through active engagement and shared care with local providers for a network approach.

Treatment objectives:

Delivery of evidence based treatment plans (or best practice treatment in rare disorders where limited evidence exists). This should lead to improved treatment outcomes (reduced mortality and co-morbidity) and maximisation of patient's functional ability through best practice multi-professional management strategies

Integration of patient care across departments within centres (e.g. between endocrinology surgical and radiological services and A&E and inpatient wards) with audited standardised flagging protocols in place

Consistent and equitable decision making about the use of off license therapies in refractory or relapsing disease

Smooth transition of young people from adolescent services supported initially by joint transitional clinics with support from clinicians from both paediatric and adult services

Aftercare objectives:

Appropriate shared care arrangements using standardised shared-care protocols between specialties, with local and national services, for the management of co-morbidities directly associated with the patients rare disease, delivered as close to patients homes as possible.

Continuity of care in long term follow up with access to specialist services being maintained

Detailed audit of patient outcomes / experience and the dissemination of best practice. For example, it is proposed that this activity would form the basis of a national registry for some rare endocrine tumours and autoimmune diseases

2.2 Service description/care pathway

Adult Specialist Endocrinology Services will include services provided by Adult Specialist Endocrinology Centres for specified conditions. The service will include out-reach when delivered as part of a provider network.

The service is commissioned to provide:

- Assessment, diagnosis and management of adolescents and adults with endocrinology disorders that fall within the scope of this specification as defined in section 2.2.8.
- Establish and restore a good equilibrium in patients as soon after diagnosis as possible by refining dosage, monitoring bloods, day curve analysis etc.
- Surgical treatment for patients with endocrine disorders of the thyroid, parathyroid, adrenal, pituitary, and endocrine pancreas.
- Provision of emergency, elective and planned care.
- Raising awareness among General Practitioners (GPs) and secondary care services on presentation of suspected endocrine conditions, with particular note to onset of life threatening endocrine disorders to ensure timely diagnosis and treatment where appropriate.
- Crisis prevention/management of life threatening complications that would typically occur in a non-endocrine setting, surgery or accident and emergency department. Service to develop and distribute patient information and best practice protocol to wider clinical staff/paramedics who may be required to manage an endocrine emergency.
- Long term follow up for patients with a chronic endocrine condition, where clinically appropriate and there is a clear evidence base, in the specialist service to enable better management and prevention of emergency situations.

- Education on self-management, counseling support and long-term follow up monitoring for patients with chronic endocrine conditions.
- Close working relationship with designated site specific cancer services.
- Close working relationship with local endocrinology services to ensure as much care as possible is delivered closer to home. Patients should continue to be supported and monitored by specialist centre in conjunction with local services as indicated.
- Advise primary care on management of condition, treatment plan and follow up monitoring arrangements as required e.g.: frequency of thyroid function test in hypo pituitary patients.
- Provision of dedicated adolescent transfer service to adult care.

Multi-professional group membership

The adult specialist endocrinology service should consist of a multi-professional group with specialist experience in treating site-specific endocrine disease. Not all centres will have all the skills and expertise required to deliver all specialist endocrinology services. It is important that the core multi-professional group reviews all new cases referred to the specialist service. The team should have agreed guidelines for the management of endocrine cancer patients as outlined in the Cancer Peer Review measures.

Note: Please refer to appendix 1 for individual adult specialist endocrinology multi-professional group members.

The service should have agreed formal links, clinical policies and care pathways with the relevant site specific cancer network, e.g.: Head & neck network (for thyroid cancer), brain & central nervous system (CNS) network (for pituitary disease)

Dedicated area are to be provided in each commissioned unit for endocrine investigations.

Imaging and pathology

Imaging and pathology services must be available to the multi-professional group in line with the network agreed guidelines for these services. The pathology services should comply with Clinical Pathology Accreditation (UK) Ltd (CPA) and the Human Tissue Authority (HTA) and should complete the Royal College of Pathologists' minimum dataset.

Genetic testing

The adult specialist endocrine multi-professional group should have embedded clinical genetics services to provide counseling and specialist genetic testing. There should be formal guidelines and pathway for referral to regional genetic services, and recognised funding streams for genetic testing requested from endocrinology via CPA accredited diagnostic laboratories.

Genetic testing and referral to regional genetic services for patients in which a

genetic condition is suspected, for example congenital adrenal hyperplasia (CAH), familial medullary thyroid cancer and adrenocorticoid cancer, inherited phaeochromocytoma or paraganglioma (extra adrenal phaeochromocytoma) and multiple endocrine neoplasia (MEN) etc

Genetic testing, reporting, counselling and laboratory activity are required to be delivered in line with the standards set out in the Medical Genetic service (all ages) service specification.

Medication

Medication to be prescribed and administered against agreed best practice guidelines and national policy / guidelines for somatostatin analogues, pegvisomant, mitotane, cinacalcet, tolvaptan, teriperatide, somatostatin analogues, sunitinib and other tyrosine receptor kinase inhibitors, everolimus and other mammalian target of rapamycin (mTOR) inhibitors. Particular hormone replacement medication should be prescribed as the branded product, for example Ferring DDAVP (demopressin acetate) (generic are less active) for diabetes insipidus, which has been used successfully for years (generics less active). Repeat prescribing for life long endocrine medication should be on a minimum of 56 day prescription.

Surgery

Surgery can occur in other regional centres as long as there is a clearly agreed clinical network arrangement and shared care policies in place with the adult specialist endocrinology multi-professional group team. Network configuration, as outlined in Provision of Services for Patients with Surgical Endocrine Disorders, British Association of Endocrine Surgeons (BAETS), 2010

British Association of Endocrine Surgeons recommend that the thyroid surgeon working in thyroid cancer should perform a minimum of 20 thyroidectomies and central neck dissections per annum. In any given region that is likely to compromise 70 or 80 new cases of cancer per annum.

Any centre

Thyroid malignancy surgery, therapeutic benign thyroid surgery, initial thyroid surgery for suspected follicular /papillary carcinoma, retrosternal goiter, thyroidectomy for thyrotoxicosis, initial surgery for primary hyperparathyroidism, and renal hyperparathyroidism (only with appropriate renal unit)

Specialist regional centre

Thyroid surgery for known medullary carcinoma, surgery for locally advanced thyroid carcinoma, recurrent thyroid carcinoma, prophylactic / therapeutic cervical node dissection, re-operative/mediastinal surgery for hyperparathyroidism, adrenal surgery, pancreatic endocrine tumours and familial endocrine syndromes

Chemotherapy and radiotherapy treatments

Chemotherapy and radiotherapy treatments are to be delivered in line with agreed NICE clinical guidelines and to national standards. Robust processes must be place for making decisions on drugs that have not been appraised by NICE. Chemotherapy and radiotherapy are not covered in this service specification. Radioactive iodine needing an Administration of Radioactive Substances Advisory Committee (ARSAC) license.

Treatment

The medical and surgical management of the following conditions is included within the national endocrinology specialised service. The following treatment modalities are subject to commissioning policy:

Specialist thyroid conditions Specialist Thyroid Conditions includes all thyroid malignancies (differentiated thyroid cancer, medullary thyroid cancer and thyroid lymphoma, anaplastic carcinoma) and complex parathyroid conditions in pregnancy, hypoparathyroidism and “complex problems of calcium/phosphate handling”.

Medical management (subject to commissioning policy) may include:

- All thyroid cancer patients to be discussed at multidisciplinary team with review of imaging, cytopathology, histopathology and biochemical tests.
- Differentiated thyroid cancer: minimum of 10 years follow-up then devolved to non-specialist endocrine service. Low/high dose ablative 131I treatment. Ultrasound (US) neck and stimulated thyroglobulin (Tg) monitoring at 12 months. Monitoring of thyroid function tests (TFT). Subsequent Tg monitoring annually. Iodine uptake scans, positon emission tomography-computed tomography (PET-CT), US and magnetic resonance imaging (MRI) as required. Suppressive T4 treatment according to risk stratification.
- Medullary thyroid cancer: urinary/plasma metanephrines prior to surgery, Life long follow-up in tertiary centre. Calcitonin monitoring. Imaging: US scanning, Nuclear Medicine investigations and/or PET-CT scanning, MRI, genetic testing.
- Lymphoma: refer to haematology multidisciplinary team.
- Total body irradiation with iodine (TKI) treatment for advanced/metastatic disease as required.

Surgical treatment (subject to commissioning policy) may include:

- All thyroid cancer surgery including diagnostic hemithyroidectomy ± completion surgery total thyroidectomy, lymph node surgery (neck and rarely mediastinum), surgery for recurrent thyroid cancer and metastases, TKI treatment
- Radioiodine administration

Calcium/bone conditions

Calcium/Bone Conditions includes complex calcium and phosphate handling conditions such as complex primary hyperparathyroidism (recurrent/with bone complications/localization issues/familial), osteogenesis imperfecta, familial

hypocalcaemic hypercalcaemia, hypoparathyroidism and Paget's disease of bone and complex parathyroid conditions in pregnancy, hypoparathyroidism and "complex problems of calcium/phosphate handling".

Treatment (subject to commissioning policy) may include:

- Medical management - Outpatients assessment, multidisciplinary team review, scans, tests and medication to strengthen bones (teriparatide). Follow up in tertiary centre. Renal Ultrasound, DXA scan, vertebral morphometry assessment, 24hr urine calcium, sestamibi, single photon emission CT (SPECT-CT), US neck, Computerised Tomography (CT), Magnetic Resonance Imaging, parathyroid hormone venous sampling, prescribing and administering cinacalcet.
- Hearing assessment, dental assessment, intravenous (IV) bisphosphonates, denosumab, genetic testing & counselling, vertebroplasty, kyphoplasty, occupational therapy, social worker, physiotherapy.
- Surgery includes parathyroid surgery, open parathyroidectomy, minimally invasive parathyroidectomy, surgery for renal hyperparathyroidism, mediastinal surgery – first time operation and reoperative intervention, spinal corrective surgery, intramedullary rods and nails and other appropriate surgery outlined in agreed national clinical protocols.

Pituitary/hypothalamic conditions

Pituitary/hypothalamic conditions include all pituitary, hypothalamic conditions, adrenal insufficiency and complex pituitary conditions in pregnancy should be initially reviewed through the central multi-professional group.

Treatment (subject to commissioning policy) may include:

- Outpatient assessment, multidisciplinary team review, scans (pituitary and hypothalamus +/- gadolinium), tests (e.g.: inferior petrosal sinus sampling, insulin tolerance tests, glucose tolerance tests, synacthen tests)
- Family cascade screening after genetic diagnosis (refer to Genetic Medical Services)
- Pituitary surgery (transsphenoidal and transcranial surgery. Endoscopic transsphenoidal / transnasal)
- Pituitary stereotactic radiation therapy. Patients are required to have counseling prior to treatment, with all the potential complications that can arise from irradiating the pituitary gland discussed. Stereotactic radiation therapy for pituitary disease is to be commissioned in dedicated pituitary clinics in a limited number of centres and consider where appropriate 'single fraction' radiotherapy. This is due to the challenges in planning treatment of pituitary disease and the risk of blindness. The treating team should include surgeons, nurse specialists, radiographers expert in stereotactic radiation therapy and physicists. (Service provision for this intervention is required to be delivered in line with the stereotactic radiotherapy service specification).

Note: Brain and other CNS tumour improving outcome guidance (IOG) describes the

operational standards for multidisciplinary teams managing pituitary disease.

Adrenal conditions

Adrenal conditions includes all adrenal conditions including congenital adrenal hyperplasia, adrenal insufficiency, adrenal Cushing's Syndrome, hyperaldosteronism, autoimmune adrenal failure and its associated endocrine and other autoimmune conditions pheochromocytoma, adrenocortical carcinoma, complex adrenal conditions in pregnancy and bilateral adrenalectomy for adrenocorticotrophic hormone (ACTH) dependent Cushing's Syndrome.

Treatment (subject to commissioning policy) may include:

- Outpatients assessment, multidisciplinary team review, scans (MRI, CT), tests (adrenal vein sampling (AVS) by bilateral adrenal vein catheterisation, aldosterone and renin secretion), medication (steroids) and consideration for surgery.
- Adrenal radiology: CT, PET-CT, MRI, Metaiodobenzylguanidine octreotide scan.
- Adrenal pathology: Weiss score/Aubert score for adrenocortical carcinoma/adrenal incidentaloma, pheochromocytoma of the adrenal gland scaled score, Advanced immunohistochemistry.
- Follow up in tertiary centre.
- Mitotane and monitoring of mitotane concentrations.
- Chemotherapy: in addition to mitotane therapy in selected cases.
- Radiotherapy to be administered by cancer multidisciplinary team.

Surgery (subject to commissioning policy) may include:

- Adrenal surgery (laproscopic adrenalectomy, open adrenalectomy sometimes in collaboration with other surgical specialties).

Neuro-endocrine tumours

Neuro-endocrine tumours treatment would include carcinoid syndrome, insulinoma, gastrinoma, glucagonoma, paraganglioma, vipomas and neuro- endocrine tumours outside the gut (bronchial, thymic)

Treatment (subject to commissioning policy) may include:

- Outpatients assessment, multidisciplinary team review, scans (CT, MRI, ultrasound, Octreotide), tests (urinary 5-hydroxyindoleacetic acid (5HIAA), Fasting gut hormone profile, 72 hour fast) and medication (octreotide LAR, Somatuline Autogel, peptide receptor radionuclide therapy (PRRT), hepatic artery embolisation).
- Surgery (Hepatobiliary , thoracic).
- Treatment & follow up in tertiary centre.

Familial Endocrine Conditions

Familial Endocrine Conditions which need genetic markers include multiple

endocrine neoplasia Type 1, Type 2 a or b, familial medullary carcinoma, caps Von Hippel Lindau disease, neurofibromatosis, Carney complex, familial paraganglioma syndromes and familial medullary carcinoma.

Treatment (subject to commissioning policy) may include:

- Screening (biochemical, radiological) and genetic testing. Watch and wait approach.
- Outpatient assessment, multidisciplinary team review, scans, tests (fasting gut hormone profile, Calcium, parathyroid hormone test (PTH), urine and plasma metanephrines) and medication.
- Family cascade predictive testing via the regional genetic centres. Surveillance of unaffected mutation carriers with imaging, hormone profiling, urine and plasma metanephrines, timing of surgery.
- Surgery.
- Treatment & follow up in tertiary centre.

Reproductive conditions

Reproductive conditions including intersexual states (genetic malformation, etc)

Treatment (subject to commissioning policy) may include:

- Outpatients assessment (endocrine).
- Multidisciplinary team review (endocrine, genetics, gynaecology, fertility) Imaging (ultrasound, CT, MRI, hysterosalpingogram, endoscopy).
- Endocrine assessment (urine and serum including sex steroids, pituitary hormones, adrenal function, tumour markers).
- Short synacthen tests, dexamethasone suppression tests.
- Genetic analysis including karyotype and mutational analysis with appropriate referral to regional genetic service.
- Fertility assessments (endocrine profiles, seminal fluid analysis).
- Medication (including sex steroid replacement, adrenal hormone replacement, emergency replacement regimens) Fertility treatments including recombinant gonadotrophins and clomiphene).
- Follow up in tertiary centre.
- Surgery includes genital reconstructive surgery, surgical sperm retrieval and gonadectomy.

The service should be patient centred and should respond to patient and carer feedback. Excellent communication between professionals and patients is particularly important and can avoid complaints and improve patient satisfaction.

Self-care and education

Every patient and family / carer must receive information about their condition in an appropriate format. The information must cover:

- Description of the disease.
- Management of the disease within the scope of the commissioned service as

described in the specification, clinical pathways and service standards including importance of:

- Drugs and other treatments commissioned in the clinical pathway
- Self-management and care including when extra steroid cover is needed
- Psychological and social support
- Dietary support information
- Access to appropriate patient support group
- Contact details of the patient’s allocated named nurse

The service must also provide education to patients and carers on:

- Routine training and regular refresher training in injections of hydrocortisone, as part of annual clinical review or as an annual reminder letter from the GP practice, inviting patients to see a practice nurse for a refresher session
- Safe management and instruction of their condition and when accessing non-endocrine care or emergency care as appropriate
- Symptoms of concern and contact details in case of emergency

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

*Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

The Endocrinology Specialist service is commissioned to provide and deliver high quality medical and surgical treatment for patients with one of the following conditions:

Specialist thyroid conditions includes all thyroid malignancies (differentiated thyroid cancer, medullary thyroid cancer and thyroid lymphoma, anaplastic carcinoma) and complex parathyroid conditions in pregnancy, hypoparathyroidism and “complex problems of calcium/phosphate handling”.

Calcium/bone conditions includes complex calcium and phosphate handling conditions such as complex primary hyperparathyroidism (recurrent/with bone complications/localization issues/familial), osteogenesis imperfecta, familial hypocalcaemic hypercalcaemia, hypoparathyroidism and Paget’s disease of bone and complex parathyroid conditions in pregnancy, hypoparathyroidism and “complex problems of calcium/phosphate handling”.

Pituitary/hypothalamic conditions include all pituitary, hypothalamic

conditions and complex pituitary conditions in pregnancy.

Adrenal conditions includes all adrenal conditions including congenital adrenal hyperplasia, adrenal Cushing's syndrome, hyperaldosteronism, pheochromocytoma, adrenocortical carcinoma, complex adrenal conditions in pregnancy and bilateral adrenalectomy for ACTH dependent Cushing's Syndrome.

Neuro-endocrine tumours treatment would include carcinoid syndrome, insulinoma, gastrinoma, glucagonoma, paraganglioma, vipomas and neuro-endocrine tumours outside the gut (bronchial, thymic)

Familial endocrine conditions include multiple endocrine neoplasia Type 1, Type 2 a or b, familial medullary carcinoma, caps Von Hippel Lindau disease, neurofibromatosis, Carney complex, familial paraganglioma syndromes and familial medullary carcinoma.

Reproductive Conditions including intersexual states (genetic malformation, etc)

Patients can be referred directly from general practitioners or by hospital consultants for medical or surgical assessment and management of specialised endocrine diseases. Once referred the patient will be assessed by a specialist multi-professional team.

The service is accessible to all patients with a suspected specialist endocrine condition regardless of sex, race, or gender. Providers require staff to attend mandatory training on equality and diversity and the facilities provided offer appropriate disabled access for patients, family and carers. When required the providers will use translators and printed information available in multiple languages.

The provider has a duty to co-operate with the commissioner in undertaking Equality Impact Assessments as a requirement of race, gender, sexual orientation, religion and disability equality legislation.

2.4 Any acceptance and exclusion criteria

Referrals will be usually accepted from general endocrinologist, though it may be appropriate for directly GP referral. The service has a duty to query the content of a referral prior to accepting it if the information provided does not indicate that the patient has a condition that fits into the specialist endocrinology service. If a service chooses to query a referral it must do so within 48 hours in conjunction with the senior clinician in the service.

Patients who do not have a rare endocrine condition that requires the expertise of a specialist endocrinology service (as described above) are excluded from this service.

Patients with the following non-specialist endocrine conditions are managed in either primary or secondary care services:

Thyroid:

- Routine management of thyrotoxicosis.
- Routine management of solitary thyroid adenomas and multinodular goitre.
- Routine management of thyroiditis.
- Routine management of hypothyroidism.
- Routine management of amiodarone and thyroid dysfunction.

Pituitary:

- Microprolactinoma.
- Routine management of hypopituitarism in liaison with the specialist centre during establishment thereof.
- Initial assessment of pituitary incidentalomas.
- Assessment on management of hyponatraemia and the syndrome of inappropriate antidiuretic hormone (ADH).

Adrenal:

- Diagnosis and initial assessment of adrenal insufficiency.
- Assessment of adrenal incidentalomas.

Reproductive:

- Assessment of hirsutism and polycystic ovary syndrome.

Menopausal disorders:

- Male hypogonadism and androgen replacement therapy.
- Gynaecomastia.
- Erectile dysfunction.
- Assessment of male infertility.

Endocrine disorders of pregnancy:

- Thyroid disorders.

Calcium and bones:

- Assessment of hypercalcaemia.
- Management of uncomplicated primary hyperparathyroidism.
- Investigation and management of uncomplicated vitamin D deficiency.
- Osteoporosis.

Miscellaneous:

- Hypoglycaemia.
- Obesity.
- Endocrinology of critical illness.

2.5 Interdependencies with other services

Co-located Services

The specialist endocrinology multi-professional group service providers are leaders in the NHS for patient care in this area. They provide a direct source of advice and support when other clinicians refer patients into the regional specialist services. This support will continue until the patient is transferred into the regional specialist centre or it becomes apparent that the patient does not have one of the agreed rare endocrine diseases outlined in section 2.2.8 above.

In addition, the service should be co-located with specialist diagnostic imaging and Interventional radiology services.

Interdependent Services

The service is required to form part of the cancer network site-specific group including head & neck multidisciplinary team for thyroid cancer and brain and CNS multidisciplinary team for pituitary cancer and to agree shared care pathway / arrangements with national endocrine services for congenital hyperinsulinism (chi) service and insulin resistant diabetes service.

Related Services

The service is required:

- To provide education within the NHS to raise and maintain awareness of endocrine disease (including endocrine cancers) and their management.
- To form a relationship with local health and social care providers to help optimise any care for endocrine disease provided locally for the patient. This may include liaison with consultants, GPs, community nurses or social workers etc.

3. Applicable Service Standards

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

Please refer to section 1.1, paragraph 3

4. Key Service Outcomes

Clinical outcomes:

- Mortality: In and out of hospital mortality (including cause of death). Comparison with published survival data.
- Post operative morbidity: vocal cord palsy & hypocalcaemia after thyroidectomy, cure rates for hyperparathyroidism, open versus laparoscopic procedures for adrenal disease.
- Remission and relapse rates: Using recognised disease specific measures of disease activity.
- Disease related damage: Using recognised disease-specific damage indices.
- Quality of life.
- Participation in clinical trials.
- Number (and outcome) of adrenal surgical procedure.
- Number (and outcome) of pituitary operations.
- Number (and outcome) of total thyroidectomy (cancer and non- cancer).
- Mortality from Neuro-endocrine tumours.
- Disease cure for patients with eg Pheos, Cushings Disease.
- Disease remission for patients with eg Acromegaly.
- Post-surgical morbidity.
- Quality of life in patients with Specialist Endocrine disease.

Process outcomes:

- Waiting times: Time to operation, time from referral to operation from hospital data systems.
- Post operative morbidity length of stay, reoperation rates, readmission rates.
- Patient / carer satisfaction: Questionnaire survey.
- Access to support groups and education: Questionnaire survey plus patient/ carer participation.
- Maintenance of Disease Registry: Rare Bone Disease registry (in development).
- Evidence of programme of joint working with non-specialist centres: Shared care protocols, outreach clinics.
- Contribution to surgical data registry (eg British Association of Endocrine & Thyroid Surgeons).
- Collection of standardized and coded activity and outcome data.
- Activity data should be collected in cases of i) Use of off-label drugs, and ii) Management of rare diseases.

5. Location of Provider Premises

The specialist services are to be:

Regionally located and provided on a network model to ensure there is consistent and equitable national coverage.

Provide outreach across each region and ensure that there is appropriate coverage to meet the population needs according to clinical need

Centres will be with based at:

- Cancer centres in the UK that are already designated to manage malignant neoplasms like thyroid malignancy and neuroendocrine tumours, or;
- Network lead specialist centres - to be agreed. Not every centre will provide all specialist endocrine services.

Stereotactic radiosurgery for pituitary disease to be commissioned in dedicated pituitary clinics in a limited number of centres in the UK.

Interim for adoption from 01/10/13

Appendix 1:

Individual specialist endocrinology multi-professional group members.

Specialist thyroid conditions multi-professional group members:

Core members:

- Endocrinologist.
- Endocrine nurse specialist.
- Radiologist with expertise in thyroid imaging including ultrasound.
- Thyroid pathologist.
- Radiotherapist/oncologist.
- Thyroid surgeon.
- Nuclear Medicine Physicians.

Extended members:

- Administration of Radioactive Substances Advisory Committee (ARSAC) license holder.
- Orbital surgeon.
- Clinical geneticist.

Calcium/bone multi-professional group members:

Core members:

- Endocrinologist.
- Endocrine nurse specialist.
- Radiologist with expertise in parathyroid imaging.
- Parathyroid surgeon.
- Nuclear medicine physician and ultrasound.

Extended members:

- Dual energy X-ray (DXA)-scanning.
- Clinical biochemist.
- Clinical Geneticist.

Reproductive multi-professional group members:

Core members:

- Endocrinologist.
- Endocrine nurse specialist.
- Radiologist with expertise in pelvic ultrasound.

Extended members:

- Reproductive gynaecologist.
- Medical obstetrician.
- Clinical geneticist.

- Paediatric endocrinologist.
- Clinical Psychologist.

Pituitary/hypothalamic multi-professional group members:

Core members:

- Endocrinologist.
- Endocrine nurse specialist.
- Neuro-radiologist+ radiologist for inferior petrosal sinus sampling.
- Neuro-pathologist.
- Pituitary surgeon.

Extended members:

- Radiotherapist/oncologist.
- Clinical psychologist or counsellor.
- Established multi-disciplinary team network.

Adrenal multi-professional group members:

Core members:

- Endocrinologist.
- Endocrine nurse specialist.
- Radiologist.
- Adrenal surgeon.
- Oncologist/radiotherapist.

Extended members:

- Adrenal venous sampling.
- Anaesthetist (for phaeochromocytoma).
- Clinical geneticist.

Neuro-endocrine tumours multi-professional group members:

Core members:

- Endocrinologist.
- Endocrine nurse specialist.
- Radiologist.
- Upper gastrointestinal surgeon/Hepatobiliary & Pancreatic surgeon.
- Nuclear medicine specialist.

Extended members:

- Clinical geneticist.
- Oncologist.

Familial Endocrine Disorders multi-professional group members:

Core members:

- Endocrinologist.
- Endocrine nurse specialist.
- Radiologist.
- Thyroid Parathyroid adrenal surgeon.

Extended members:

- Clinical geneticist.
- Upper gastrointestinal surgeon.
- Pituitary surgeon.
- Genetic counsellor.

The above multi-professional group should have agreed formal links, clinical policies and care pathways with the relevant site specific cancer network, e.g.: Head & neck network, brain & CNS network (Pituitary).

Interim for adoption from 01/10/13