SCHEDULE 2 – THE SERVICES

Service Specifications

Service Specification No.	**E10s**
Service	**Complex Gynaecology Services – Recurrent Prolapse including laparoscopic surgery**
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

National/local context and evidence base

Pelvic organ prolapse is when the organs inside of the pelvis, such as the uterus, urethra or bladder, protrude toward or through the opening of the vagina. This is considered to be a common health problem and there is a 1 in 10 lifetime risk of a woman requiring surgery for this problem. 40,000 prolapse (and incontinence) surgeries are performed to address this issue annually in England and Wales.

Patients with symptoms and signs of recurrent prolapse after previous surgery, defined in the International Urogynaecological Association (IUGA)/ International Continence Society (ICS) joint report, as "prolapse arising from the same site that will require specialist treatment services". It is estimated that the requirement for site specific recurrent prolapse surgery is 3-10% (Kapoor DS 2009; Diwadkar GB 2009; Miedel 2008). This equates to approximately 2-4000 cases annually.

The complicated nature of many of these cases dictates that patients should be managed in units that offer care delivered by sub-specialist Urogynaecologists (and on some occasions by female Urologists) working in a multi-disciplinary team (MDT) structure. The care of these women with site specific recurrent prolapse should also be provided within selected hospitals with the appropriate co-located services. They should be able to offer a comprehensive range of treatments and surgical procedures as there is no single procedure that is appropriate for all situations. Locating these services in centres with high numbers of patients should ensure improved treatment outcomes.

Service quality assurance for patients

Specialist Units:

Specialist units that provide this service will also need defined links to other services (Urology, colorectal, continence services and radiology) and should be co-located with these relevant services. These units will have sub-specialist Urogynaecologists as their lead clinicians, as defined by the British Society of Urogynaecology (BSUG). The unit will deliver a comprehensive range of prolapse treatments applicable to a broad range of scenarios in compliance with NICE guidelines. In addition:

1. In order to maintain expertise and surgical experience, specialist units will be able to demonstrate a caseload of complex and recurrent prolapse surgical procedures ideally in excess of 20 cases per year (on average, over 3 or more years).

2. Some women may require prolapse surgery augmented with mesh. This may be undertaken either laparoscopically or vaginally. Only units which have surgeons who have the training and expertise with a caseload on average of 10 of each or more per annum over 3 years should perform this surgery. Individual surgeons should be performing more than 10 mesh cases (laparoscopic or vaginal each) per annum.

3. Units that perform fewer than 20 complex and recurrent cases or less than 10 mesh cases per year must have special arrangements for local clinical governance in place and must operate under the auspices of a larger regional MDT. It is intended that, over time, a small number of Specialist Units will emerge and a required minimum number of complex surgical cases can be proposed based on the evidence of outcomes data.

4. It is important that laparoscopic surgical procedures to treat prolapse, including primary procedures such as hysteropexy, sacrocolpopexy (following a hysterectomy not undertaken for prolapse) and paravaginal repairs are performed in units which have the appropriate expertise in laparoscopic urogynaecology to ensure that all the functional and anatomical issues are addressed. The recommended case load per individual is 10 cases per year (defined as an average over a 3 year period) which may form part of the above. Units doing less than this should do so only with written agreement of their governance committee and the agreement of the CCG.

5. Multi-professional and multi-disciplinary input is required because the patient often has co-morbidities which render the care of her gynaecological disorder especially complex e.g. uterine prolapse, desiring a further pregnancy, urinary/faecal incontinence accompanying prolapse. These type of issues should be seen by a sub-specialist centre co-located with other specialised services within the setting of an MDT.

6. The MDT must be comprise of 2 Urogynaecologists (or 1 urogynaecologist and a female urologist/coloproctologist), specialist nurses / physiotherapists and a coloproctologist where appropriate. There should also be defined links to other related services (eg radiology, neurology, psychology), which should be co-located with them. The provider should deliver high quality services within an agreed network of providers whose population may also use this service.

7. The MDT must convene at least 12 times per year. In order to be quorate, the meeting must be attended by at least 3 members, two of whom must be urogyaecologists (or 1 urogynaecologist and a female Urologist/coloprotcologist).The MDT must ensure documented discussion of complex cases, review of important diagnostic tests and prospective audits of activity and outcomes. National databases, such as the BSUG

databases, should be used to record activity for all cases and yearly audits of surgical outcomes should be undertaken with national benchmarking between Specialist Units. There is a progression of requirements based on this as an appendix below.

It is expected that this type of surgery will be performed by sub-specialist Urogynaecologists. They will provide one specialist clinic per week and will devote at least 50% of their clinical practice to urogynaecology.

Training:

1. Many consultants currently have expertise and experience gained through traditional training schemes in Gynaecology and Urology with subsequent development of specialist practice as consultant urogynaecologists. It is anticipated that future consultants will be able to demonstrate sub-specialist training. In gynaecology, defined training schemes and curricula exist for urogynaecology, including Subspecialist Training Schemes or ATSM modules.

2. Some women will require surgery employing laparoscopic techniques. It is essential that laparoscopic surgical procedures to treat prolapse be performed in units that have the appropriate expertise.

3. Units will need a minimal caseload to develop and maintain this expertise. These caseloads are in accordance with the Royal College of Gynaecologists (RCOG) projections for workforce planning which aims to produce a core of 55 sub-specialist Urogynaecologists and 350 special interest Urogynaecologists. The Regional/BSUG accredited urogynaecology units currently established in England all have at least two sub-specialist urogynaecology surgeons working within the units who could manage the expected workload. This service may be provided by consultants working in more than 1 unit providing the service is combined.

Commissioning and Accreditation of Specialist Units:

1. Providers wishing to offer treatment for complex and recurrent prolapse will be required to demonstrate evidence and compliance with the criteria set out in this specification. Local commissioning teams must ensure that providers wishing to function as specialist units adhere to the specification criteria and provide evidence of compliance.

2. Accreditation of specialist units by professional bodies such as BSUG will be regarded as evidence of compliance, and these bodies will ensure that accreditation standards are commensurate with those for specialist unit status.

3. Units which are unable to provide such services or which cannot provide evidence of compliance with the required standards will need to develop tertiary referral pathways to a specialist centre and will be expected to discontinue these services locally.

4. Specialist units must provide evidence of ongoing compliance with the above criteria every 3 years, including results of relevant clinical audits. When there is a change in consultant personnel within the MDT, the provider must inform the commissioning body and the accrediting body (where appropriate) so that Specialist Unit status can be reconfirmed.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

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

Domain 3 of the NHS outcomes framework focuses on helping people to recover from ill-health or following injury. This includes recovery from elective surgery including Urogynae surgery. Combining indicators which monitor adverse outcomes (showing progress in reducing cases in which recovery has been interrupted by emergency admissions) with those that measure positive progress in recovery (PROM), demonstrates the NHS's contribution to minimising the adverse impact of ill-health and injury upon the quality of life of those affected.

The main measures to be assessed for adverse outcome within the remit of this specification are:

1. Emergency readmissions within 30 days of discharge from hospital following elective surgery

2. Patient Reported Outcome Measures (PROM).

There is currently no recommended PROM by the DH for prolapse and incontinence, but there are several already in use including the ICIQ, KHQ, ePAQ. It is expected that units undertaking this work utilise the BSUG database (or equivalent) with an annualised number of cases in excess of 200 pelvic floor surgeries

Domain 4 of the NHS outcomes framework seeks to ensure patients have a positive experience of care. For the purposes of this specification , this will be measured using the Overall Patient Experience score which is the average (mean) of five domain scores

- Access & Waiting
- Safe, high quality co-ordinated care
- Better information, more choice
- Building closer relationships
- Clean, friendly, comfortable place to be

2.3 Service Outcomes

- Services will provide a tertiary service to support women requiring specialist support within a network of care and pathways.
- Eligible women will be referred using a defined referral system that can be audited for waiting times.
- There will be an agreed planned and mapped pathway of care for women whose primary procedure for urinary incontinence or prolapse repair has failed or who has complications arising from treatment of urinary incontinence or prolapse including problems arising from mesh implantation.
- The Service will be part of a mult-idisciplinary team working together, networking and linking with other healthcare services across both community and hospital settings.
- A discharge plan will be prepared offering support and facilities required providing care at home
- Outcome measures including relief of symptoms and satisfaction with care will be measured and audited.
- The provider will be expected to use evidence based approaches and to demonstrate efficiencies whenever possible.
- Appropriate referrals to specialist colleagues will be documented and GP informed of any transfer of care
- It is the responsibility of the provider to recruit/provide suitable and appropriately competent and qualified personnel in the provision of this service. When advanced surgical techniques such as laparoscopic surgery are required the unit will have available clinicians who have the appropriate training in both Urogynaecology and laparoscopic surgery.
- All patients should be under the care of an experienced multidisciplinary team. This should include a Urogynaecologist, a specialist nurse, a physiotherapist and a urologist and colorectal surgeon where required.
- Providers will enter all procedures involving implants on a national registry and organise follow up and audit of outcomes.

3. Aims and objectives of service

To provide patient centred specialist care for women with recurrence of symptoms or de novo symptoms following surgical treatment of urinary incontinence or pelvic organ prolapse.

The primary aims are:

1. To provide safe, effective and evidence based pathways of care to women with recurrent

prolapse

2. To perform an extended or advanced assessment of the anatomical and functional problems which will include assessment of:
- Anatomical disruption
- Urinary function
- Bowel function
- Sexual function
- Appropriate investigations of lower urinary tract and gastro-intestinal tract function

3. To provide counselling about the surgical and non-surgical treatment options and to offer the appropriate laparoscopic and open surgical treatment (including vaginal mesh where appropriate)

4. This will include treatments outlines in current NICE guidelines
- Conservative and lifestyle management, where appropriate
- Standard vaginal surgery for repeat prolapse including vault prolapse
- Laparoscopic (and open) sacrocolpopexy and sacrohysteropexy
- Vaginal mesh augmented prolapse repair

5. To provide continuity of care through the whole care pathway encompassing other specialised services included within the pathway

3.1 Service description/care pathway

The service outlined in this specification is for patients ordinarily resident in England. Specifically, this service is for women who have developed complications, including failure, of primary surgery to treat pelvic organ prolapse. They will:

- Be referred either from primary care or secondary care through local networks to Specialist units (as defined above)
- Be assessed in the outpatient setting by a named Consultant Urogynaecologist (either by training or by devoting over 50% working week to Urogynaecology practice) or where appropriately trained Urologist.
- Have appropriate investigations of lower urinary tract and gastrointestinal tract function will be performed (urodynamics, anorectal studies, radiological or ultrasound imaging)
- Discuss their treatment options a multi-disciplinary team including a subspecialist Urogynaecologist, a specialist nurse, a physiotherapist. A colorectal surgeon and urologist may also be involved where relevant as well as other allied healthcare specialties.
- Counsel patients about the management options including non-surgical and surgical treatments.
- Offer elective laparoscopic and open surgical treatments after informing the patient about the different approaches to surgery.

Services will provide the defined activities outlined below as part of a multi-disciplinary team associated with interdependent services

3.2 Management of recurrent pelvic organ prolapse / failed primary surgical treatment

Primary surgery for pelvic organ prolapse is usually performed by gynaecologists who have received additional training in urogynaecology. When primary surgery fails or there is a recurrence of prolapse there is often associated bladder, bowel and sexual dysfunction. Further surgery is technically more difficult and may require laparoscopic techniques involving implant materials (mesh) or vaginal approaches with these materials and these are not normally within the repertoire

of gynaecologists who perform primary surgery.

Techniques employing laparoscopic surgery for POP are not practised by the majority of Gynaecologists and should only be performed by appropriately trained surgeons with expertise in prolapse surgery (Urogynaecologist /Urologist with expertise in female urology).

Mesh implants (laparoscopic or vaginal) can be associated with exposure/erosion into the vagina, bladder or rectum. This surgery can be technically challenging and alternative techniques may be required which are not within the repertoire of the majority of gynaecologists. Additionally combined procedures with colorectal and urological surgeons may be required.

Such cases should be managed by centres with expertise and experience of laparascopic Urogynaecology procedures (laparascopic sacrocolpopexy and laparascopic sacrocolpohysteropexy) and/or vaginal meshes as well as removing mesh and reconstruction of the area concerned.

Units which accept referrals for such cases will have a caseload for individuals of at least 10 mesh procedures per year (averaged out over 3 years).

3.3 Management of complications of prolapse surgery

In addition to failure surgery for pelvic organ prolapse these may be followed by the following problems:

- Mesh complications (exposure and erosion)
- Urinary voiding dysfunction
- Urinary incontinence
- Urinary fistula
- Ano-rectal dysfunction including incontinence
- Dyspareunia

Investigation and management may include:

- Urodynamics (including the role of video and ambulatory)
- Imaging of lower and upper urinary tract and bowel

Treatment may include further surgery requiring tertiary level expertise.

4 Population covered

Included within individual conditions above.

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.
Specifically this service is for women who have had previous surgery for prolapse/incontinence and require specialist intervention as outlined within this specification.

4.1 Any acceptance and exclusion criteria and thresholds

- Eligible women will be referred using a defined referral system that can be audited for waiting times
- Pathways of care with auditable outcome measures will be employed.

- The service will accept referrals from other providers particularly where the referring service does not undertake the procedures the patient requires.
- The Provider will be expected to use evidence based approaches and to demonstrate efficiencies
  whenever possible.
- A discharge plan will be prepared offering support and facilities required providing care at home.
- Appropriate referrals to specialist colleagues will be documented and GP informed of any transfer of care

Exclusions: Cancers these are covered in the cancer services specifications

4.2 Interdependencies with other services/providers

i) Co-located Services
Availability of the various services (Urogynaecology, urology, colorectal surgery, physiotherapy and imaging) at the same site and easy access to the MDT has several advantages. This ensures better communication, a more efficient service and lower costs for hosting of the services.

ii**) Interdependent Services**
The delivery of this service will be within the remit of an MDT working together, networking and linking with other healthcare services across both community and hospital settings. These services include urology, colorectal services, imaging, and community.

iii) Related Services - *services either at the preceding or following stage of the patient journey*
Preceding services will include the community as well as other units which will refer to the specialist services for management of these complex conditions
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iv) Data Submission
This will be through the BSUG database and will include:
- Pre-operative
- Intra-operative
- Post-operative data on consecutive cases

5. Applicable Service Standards

5.1 Applicable national standards e.g. NICE

See Appendix 2

- NICE (2008) 'Surgical repair of vaginal wall prolapse using mesh, NICE Interventional Procedures Guidelines IPG267'

- NICE (2009) 'Infracoccygeal sacropexy using mesh for uterine prolapse repair, NICE Interventional Procedures Guidelines IPG280'

- NICE (2009) 'Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair, NICE Interventional Procedures Guidelines IPG281'

- NICE (2009) 'Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair, NICE Interventional Procedures Guidelines IPG282'

- NICE (2009) 'Sacrocolpopexy using mesh for vaginal vault prolapse repair, NICE Interventional Procedures Guidelines IPG283'

- NICE (2009) 'Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, NICE Interventional Procedures Guidelines IPG284'

- All surgeons carrying out mesh procedures for prolapse are mandated to use the BSUG database or equivalent.

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

Units providing services within the remit of this specification will be accredited by BSUG. This will ensure quality standards and a reassurance that these specialist units meet all criteria required to provide these services by an independent and competent body.

5.3 Coding

Universal coding strategies should be encouraged so that accurate workload data can be monitored across the UK for primary and recurrence incontinence. The following *recommendations* are designed to facilitate common practice between providers.

1. Code for the main procedure and any ancillary procedures performed
2. In the case of surgery for recurrent prolapse, the code Y71.3 is used.
3. In the case of surgery for recurrent prolapse following two previous procedures for the same clinical problem, the code Y71.6 is used
4. In the case of surgery for recurrent prolapse following three or more previous procedures for the same clinical problem, the code Y71.7 is used. It is recommended that further codes be introduced to denote recurrence after 4 and 5 previous procedures.
5. Prolapse in a new site different to the site of primary surgery does not constitute recurrent prolapse
6. Vault prolapse following vaginal hysterectomy for prolapse **does** constitute recurrent prolapse surgery.
7. Laparoscopic Sacrocolpopexy will be coded as P24.2 + Y75.2
8. Laparoscopic sacrohysteropexy will be coded as Q54.5+ Y75.2

Appendix One

Quality standards specific to the service

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Not Applicable			
Domain 2: Enhancing the quality of life of people with long-term conditions			
Proportion of people feeling supported to manage their condition	> 90%	Proportion of patients feeling supported assessed through questionnaires /telephone interview	Audit to evaluate causation and change in practice where feasible
Unplanned Admissions	<2%	HES data	Audit to evaluate causation and remedial action
Ability to work with this condition (Pg 32; 2.2 Updated definition	>85%	Assessed through patient assessment of their condition	Audit to evaluate causation and remedial action
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Emergency readmissions within 30 days of discharge from hospital	< 5%	HES data: Proportion of patients readmitted following surgery for their recurrent prolapse or incontinence	Audit to evaluate causation and remedial action
Patient Reported Outcome Measures (PROMs) for elective procedures	>70%	Completion of pre and post-operative ICIQ, KHQ, ePAQ or other validated questionnaires	
Domain 4: Ensuring that people have a positive experience of care			
Measuring patient experience of outpatient care. This is across three stages of the care pathway: pre-visit; during the visit to the Outpatients department; and the transition/post-visit period	> 85%	Care Quality Commission's Outpatient survey	Audit to evaluate causation and remedial action
Measuring patient experience of hospital inpatient care which is the average (mean) of five domain scores 1) Access & Waiting domain 2) Safe, high quality co-	>85%	The Care Quality Commission's Adult Inpatient Survey	Audit to evaluate causation and remedial action

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
ordinated care domain 3) Better information, more choice domain 4) Building closer relationships domain and 5) Clean, friendly, comfortable place to be domain.			
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
All Patient Safety incidents reported especially Safety incidents involving severe harm or death	98%	Reduction of Incidents compared to previous years	Audit to evaluate causation and remedial action
Measurement of Incidence of hospital-related venous thromboembolism	As per national KPIs	Number of cases per year by the number of admissions for elective surgery	Audit to evaluate causation and remedial action
Measurement of Incidence of healthcare associated infection: i MRSA bacteraemia; ii C.difficile	As per national KPIs	Number of cases per year by the number of admissions for elective surgery	Audit to evaluate causation and remedial action

Appendix Two criteria for unit approval by year 2015-19

Year	Database	Protocols	MDT	Job planning	Complex / recurrent caseload
2015-16	Registered using a database	Unit protocols	MDT to include Urogynaecologist, female urologist, physio or nurse specialist, and colorectal specialist.	job plan recognising specialist area	Individual caseload Min 10 of lap or vaginal mesh / year based on 3yr average Unit case load of complex and recurrent cases should ideally be > 20 and those between 5 and 20 per year must have special arrangements for local clinical governance
2016-17	As Above		Time in job plans for MDT	Objectives to include development needs in LUTs	As above
2017-18	Audit report of cases			MDT within job plan	> 20 cases per individual/ year
2018-19	12 months of outcome data at 3-6 months	BSUG accreditation or equivalent	Audited outcomes of MDT (patient numbers)	Multidisciplinary clinics	> 20 cases per individual / year with published outcome data

Appendix 3 - Definitions

1. **Primary Surgery-** This indicates the first procedure required for the treatment of pelvic organ prolapse (POP) in any compartment

2. **Primary prolapse surgery/different site-** A prolapse procedure in a new site/compartment following previous surgery (e.g. anterior repair following previous posterior repair)

3. **Repeat surgery/Recurrent prolapse surgery-** A repeat/recurrent operation for prolapse arising from the same site. Where combinations of procedures arise, such as new anterior repair plus further posterior repair, these should be reported separately as primary anterior repair and repeat posterior repair

4. **Complex prolapse-** Uterine prolapse in women wishing for further pregnancy or prolapse with concurrent urinary or faecal incontinence. Mesh exposure or extrusion, pain, or patient compromise such as haemorrhage

5. **Complications-** Subsequent surgery for stress urinary incontinence or faecal incontinence.

Relevant medical specialties:

Urogynaecologist - Urogynaecology is a sub-speciality of gynaecology that deals with benign disorders of the lower urinary and genital tract, principally urinary incontinence and genital prolapse

A Urogynaecologist is defined by British Society of Urogynaecology (BSUG) as a Gynaecologist who fulfils the following criteria:

- Has a dedicated Urogynaecology clinic or equivalent per week including secondary and tertiary referrals, as part of a MDT service
- Has trained in a unit that provides the full range of investigations and treatments required for training
- Has urodynamics experience and has a regular urodynamics session (minimum of 1 per month)
- Provides 3 clinical sessions of Urogynaecology per week and at least one major Urogynaecology procedure associated with pelvic floor dysfunction per working week per year.
- Regularly audits their practice eg BSUG database

- Proportion of continuing medical education (CME) in Urogynaecology or equivalent. For consultants gaining accreditation after 2010 this would require successful completion of either an advanced training skills module (ATSM) in Urogynaecology or subspecialty training.

FNUU Urology

FNUU (Functional, Female, Neurology and Urodynamic Urology) is defined by the British Association of Urological Surgeons as the sub-specialty of urology that covers the investigation and treatment of benign conditions of the lower urinary tract. It also encompasses related problems within the female genital tract. The particular focus of the sub-specialty is on disorders of function and on inflammatory conditions affecting these systems. A major component of the subspecialty is neurological urology, which covers the management of patients with neurological conditions that have an impact on urinary tract and sexual function.