

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No:	
Service	Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse
Commissioner Lead	<i>For local completion</i>
Provider Lead	<i>For local completion</i>

1. Scope

Prescribed Specialised Service

This service specification covers the management of women with complex urinary and faecal incontinence and uterine and/or vaginal prolapse combined with rectal prolapse where repeat and/or further surgical treatment is being considered following unsuccessful prior surgical procedures. Repeat surgery for incontinence and prolapse requires more expertise as the procedures used are generally more complex than the initial procedures and the potential for damaging complications is increased by the consequences of previous surgery.

This specification incorporates the previously commissioned specifications for Complex Gynaecology: Urogenital and Anorectal Conditions (E10/S/b), and Complex Gynaecology: Recurrent Prolapse and Urinary Incontinence (E10/S/d).

Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse is covered by a separate service specification.

1.2 Description

Urinary incontinence is the unintentional leakage of urine. Pelvic organ prolapse is where the apex (top) of the vagina (uterus or vault), anterior (front) vaginal wall (urethra or bladder) or posterior (back) vaginal wall (rectum) protrudes towards or through the opening of the vagina. Urinary incontinence and prolapse can be associated with faecal incontinence (unintentional leakage of bowel motion) and rectal mucosal prolapse (protrusion of the lining of the rectum towards or through the anus). Incontinence and prolapse are both very common and are treated in primary, secondary and tertiary care. Incontinence and prolapse should always be managed by clinicians with appropriate expertise who can offer a comprehensive range of treatments and surgical procedures within a multi-disciplinary team (MDT) structure.

A small number of women with incontinence and prolapse will require complex and/or more invasive specialised surgical treatment which the majority of urogynaecology and female urology units will not offer. Such treatments fall under specialised commissioning and are the subject of this service specification.

This includes:

- Women with recurrent incontinence (stress predominant) usually following prior surgical procedures and who may require more surgery.
- Some primary surgery for stress incontinence is also specialised with only a small number of cases performed annually for example colposuspension.

- Women with urgency urinary incontinence who fail to respond to Onabotulinum toxin 'A' injections as a second line treatment or who withdraw from therapy due to side effects and still require further intervention such as sacral nerve stimulation (covered in a separate NHS England policy) or ileocystoplasty (or other bowel cystoplasty procedures).
- Women requiring a primary surgery for their prolapse procedures which is less commonly performed for example laparoscopic hysteropexy.
- Women who have developed complications, including failure of previous surgery to treat pelvic organ prolapse and where further surgical treatment is being considered.
- Women who require simultaneous combined Urogynaecology/ female urology and colorectal surgery.
- Women who require specialised single compartment prolapse surgery because of the complexity of their case or associated co-morbidities for example, neurological conditions.
- **Vaginal mesh insertion to treat prolapse.**
- Women who require specialised primary incontinence surgery because of the complexity of the case or associated comorbidities (e.g. neurological conditions, complex urinary tract reconstruction, voiding dysfunction etc.)
- Simple localised excision for mesh pain following discussion and agreement with the Mesh MDT within the Specialised Mesh Removal Service (Mesh Service).

1.3 **How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners**

This service is for women requiring complex and/or more invasive specialised surgical treatment for incontinence and prolapse.

2. Care Pathway and Clinical Dependencies

2.1 **Care Pathway**

This service specification covers the management of women with complex urinary and faecal incontinence and uterine and/or vaginal prolapse, including where this is combined with rectal prolapse and for the management of women with these conditions where repeat and/or further surgical treatment is being considered following prior surgical procedures.

The Specialised Complex Urinary Incontinence and Prolapse MDT (the MDT) is central to providing high quality care for women requiring treatment of complex prolapse and urinary incontinence conditions.

The MDT must include:

Core Members:-

An appropriately trained urologist specialising in female urological conditions
An appropriately trained urogynaecologist.

Other MDT members:-

Will be determined by the complexity of the case mix and will include:-

An appropriately trained colorectal surgeon

A specialist in pain management

A pelvic pain specialist

A specialist nurse

A specialist physiotherapist

A physiologist

A specialist radiologist

Specialist imaging

A neurologist

A gastroenterologist

A neurosurgeon

(NB. The specialist gynaecologist and specialist urologist may be subspecialist urogynaecologists, urogynaecologists, gynaecologists with a special interest and Female, Neurological and Urodynamic Urologists (FNUU).

The MDT will accept referrals from non-specialised gynaecology and urology MDTs. Good communication with the referring MDT is essential to enable appropriate triage of referrals and advice for non-specialised MDTs and patients about the most appropriate treatment options. The mechanism of communication will vary but can be via teleconferencing, video conferencing and face to face MDT meetings.

Support for the MDT is required to co-ordinate the MDT and to ensure all appropriate investigations are available for the MDT meetings. The outcome of the MDT must be documented and a clear pathway established to communicate this information to the patient and the referring MDT.

Outpatient Appointments

Following the above MDT to MDT discussion all patients accepted into the specialised service will be offered an outpatient appointment to determine the diagnosis and recommend management.

Investigations

Many of the investigations will have already been performed by the referring MDT and should be made available to the MDT prior to the initial outpatient appointment. However, further or repeat investigations may be required and these can include:

- Urodynamics
- Videourodynamics
- Ambulatory urodynamics
- Ultrasound – pelvic floor and endoanal
- Anorectal studies
- Magnetic resonance imaging (MRI)
- Mercapto acetyl tri-glycine' scan (MAG3 scan)
- Barium or MR defecating protogram (magnetic resonance)
- Bowel motility studies

The investigations will allow for an extended or advanced assessment of the anatomical and functional problems which may include assessment of:

- Anatomical disruption
- Urinary function
- Bowel function
- Sexual function

Treatment Strategy

The MDT review will determine which women with complex incontinence and prolapse are suitable for further surgical treatment.

The MDT should review all patients who have had previous failed continence or prolapse procedures and the patient advised of treatment options prior to deciding on having a repeat surgery at the specialised or non-specialised centre.

Surgical Procedures

The following procedures when undertaken for repeat or complex cases are considered to be specialised surgical procedures and can only be performed in specialised centres

- Colposuspension (open and laparoscopic)
- Rectus Fascial or Fascia Lata Slings
- Artificial Urinary Sphincter
- Ileocystoplasty
- Sacral nerve stimulation for overactive bladder (subject to a separate commissioning policy)
- Laparoscopic hysteropexy
- Laparoscopic sacrocolpopexy

- Colpocleisis
- Vaginal insertion of mesh for pelvic organ prolapse
- Re-do open sacrocolpopexy

Standard vaginal surgery for repeat prolapse in the same compartment These include:

- Anterior colporrhaphy
- Posterior colporrhaphy

The following procedures will be included as part of this specification **ONLY** when performed jointly by a colorectal surgeon with a urogynaecologist or urologist specialising in female urology present. (If performed alone, these procedures are under the colorectal remit)

- Laparoscopic ventral rectopexy/ DeLormes rectopexy
- Stapled Transanal Resection of the Rectum (STARR) procedure
- Sphincter repair surgery +/- perineal reconstruction
- Dynamic graciloplasty

Procedures that involve the treatment of vesicovaginal/ urinary tract and/ or rectovaginal and anoperineal fistulae should only be undertaken in centres commissioned to provide vesicovaginal/ urinary tract fistulae (under a separate specification) and rectovaginal/ anoperineal colorectal surgery.

In a small number of women simultaneous surgery with a gynaecologist or urologist and colorectal surgeon is required, including women with complex neurological conditions such as paraplegia or multiple sclerosis.

The following procedures can be performed by non-specialist centres if agreed after discussion at the specialist MDT:

- Localised excision of minor erosion
- Mid urethral sling procedures (MUS)

Follow-up

All patients will have a single postoperative follow up visit.

In some specific cases patients will require a series of follow-up visits with the specialist nurses.

Data Management, Audit and Governance

- The management of complex and recurrent incontinence and prolapse will take place in specialist units which provide treatment by consultants working within a MDT structure.
- The MDT must convene at least once each month. In order to be quorate, the MDT must be attended by at least 3 members including the two Core Members.
- All procedures should be recorded on a national database such as the British Association of Urological Surgeons (BAUS) or British Society of Urogynaecology (BSUG) databases.
- Specialist units will provide complex incontinence and prolapse treatments in compliance with current NICE guidelines.
- All units should have The British Society of Urogynaecology (BSUG)/The British Association of Urological Surgeons (BAUS) accreditation or similar as a baseline. (It is acknowledged that non-specialised units may also have BSUG/BAUS accreditation however, this does not mean that they can deliver the specialised services outlined in this specification. This accreditation demonstrates good working practices).
- There needs to be clear documentation as to competency to perform these procedures. Advanced laparoscopic surgery and advanced open surgery is not within the repertoire of most gynaecologists/ urologists specialising in female urology who perform primary surgery. These techniques should only be performed by appropriately trained surgeons with expertise in these techniques (specialist gynaecologist / specialist urologist).
- Repeat laparoscopic surgical procedures to treat prolapse, including primary procedures such as hysteropexy, sacrocolpopexy and paravaginal repairs should only be performed in units which have the appropriate expertise in laparoscopic uro-gynaecology/ female

urology conditions to ensure that all the functional and anatomical issues are addressed. The recommended case load per individual surgeon is 10 cases of advanced laparoscopic prolapse operations per year which may form part of the above.

Vaginal Mesh

- Some women may require prolapse surgery augmented with mesh. This may be undertaken either laparoscopically or vaginally.
- Vaginal mesh is used as a successful treatment option for many women with urinary incontinence and vaginal/ uterine prolapse, however there are known complications in relation to the use of mesh resulting in significant morbidity in some women. Prior to the use of vaginal mesh, patients should be fully counselled and provided with information on all mesh and non-mesh treatment options and risks, and given time to consider their options.
- Only units with surgeons who have the training and expertise should perform this surgery. Individual surgeons should be performing more than 10 mesh cases (laparoscopic or vaginal each) per annum.
- Individual Trusts providing mesh services must use Trust appraisal systems to ensure surgeons: are appropriately trained and current in their practice; adhere to clinical guidance; comply with national data requirements and report complications.
- Use of mesh should be in line with the latest National Institute of Care and Health Excellence (NICE) guidance and professional standards.
- All adverse incidents must be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA).
- All additional reporting requirements for individual patients also apply, e.g. reporting to local incident systems, the National and Learning System (NRLS) and serious incidents to the Strategic Executive Information System (StEIS).
- All issues related to medical devices must be reported to the MRHA yellow card scheme.
- Trusts will enter all procedures involving implants on a national registry (when it is created) along with organised follow up and an audit of outcomes.
- Providers will enter all procedures involving implants on a national registry (when it is created) and organise follow up and audit of outcomes.

Mesh Complications Surgery

Mid urethral tape mesh is commonly used to treat stress urinary incontinence in women whilst vaginal mesh is occasionally used to treat prolapse. A small number of women can develop complications from vaginal mesh surgery. These complications may include:

- Vaginal exposure
- Erosion into the urinary tract
- Erosion into the bowel
- Infection
- Pain
- Fistulae
- Mesh shrinkage
- Organ perforation
- Nerve or vascular injury
- Sexual difficulty

All women with mesh complications must be discussed by the Mesh Service's Multi-Disciplinary Team (Mesh MDT) (see specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse service specification).

For vaginal mesh erosion into adjacent organs, this always requires removal of the mesh and a referral must be made to the Mesh MDT, members of whom will carry out the surgery.

For none complex mesh complications, (lump, sinus or discharge or exposure of a small amount of mesh <1cm in the vagina) mesh removal may not always be required. However, if following discussion and agreement with the Mesh MDT, simple localised excision of minor mesh erosion

can be performed by the Specialised Complex Urogynaecology/ Female Urology Conditions MDT.

For mesh complications with pain but with no erosion, input from a pain specialist and/or neurologist will be necessary. If mesh removal is advised a referral will need to be made to the Mesh Service. If following discussion and agreement with the Mesh MDT, simple localised excision for mesh for pain is indicated, surgeons in a Specialised Urogynaecology/ Female Urology Conditions Centre can perform it.

Referral Processes and Sources

Referrals will be accepted from non-specialised MDTs and directly from primary care where complex co-morbidities are identified.

2.2 Interdependence with other Services

It is expected that trusts delivering specialised complex surgery for prolapse and urinary incontinence conditions will be able to demonstrate competence in advanced open and advanced laparoscopic techniques and have access to the specialised equipment and theatres to support this.

Co-located services: Specialist gynaecology and specialist urology must be co-located. These may be subspecialist urogynaecologists, urogynaecologists, gynaecologists with a special interest and Female, Neurological and Urodynamic (FNUU) urologists. In most units the gynaecologists would be a sub-specialist however, gynaecologists with a special interest may undertake further training to develop additional expertise to attain the correct skills.

There should also be defined links to other related services (e.g. radiology, neurology, psychology, pain management and colorectal), which should be co-located.

3. Population Covered and Population Needs

3.1 Population Covered By This Specification

This service is specifically for women with complex urinary incontinence and prolapse who require complex and/or more invasive specialised surgical treatment.

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.

3.2 Population Needs

Urinary Incontinence

Stress Incontinence

In England over 10,000 stress incontinence operations are performed annually by specialist gynaecologists and specialist urologists in acute care (specialised and non-specialised). These operations are chiefly performed for primary stress urinary incontinence and are able to cure stress incontinence in about 85%.

This means:

- Approximately 1,500 patients each year will have persistent/recurrent urinary incontinence and potentially require further surgery
- Of these 1,500 approximately 75% will have a repeat successful procedures – leaving about 375 women with recurrent/persistent stress incontinence or severe primary urinary

stress incontinence requiring more specialised assessment and possibly surgery and this is the group that are included in this service specification.

Urgency Incontinence

In addition there are also a large group of women with urgency urinary incontinence who respond to primary medical and physical therapies and do not require surgery.

- Approximately 1500 women who do not respond may be managed with Intravesical Onabotulinum toxin 'A' injections. Onabotulinum toxin injection is not a specialised procedure and is not covered by this service specification.
- However, a small number of women who will be unsuitable for or fail to respond to this procedure or withdraw from the therapy due to side-effects. They may require sacral nerve stimulation or further surgical intervention and are included in this specification.
- Sacral nerve stimulation for overactive bladder is covered by a separate NHS Clinical Commissioning Policy.
- Surgical intervention for urgency urinary incontinence can include more invasive operations such as ileocystoplasty. It is estimated that 105 ileocystoplasty (or other bowel cystoplasty procedures) are performed annually and are included in this service specification. These should be performed with a colorectal surgeon with expertise in this indication.

Prolapse

In England over 40,000 women each year will undergo surgery for incontinence and/or prolapse. These operations are performed by specialist gynaecologists and specialist urologists in acute care (specialised and non-specialised).

It is estimated that of these, 10% will develop symptoms and signs of recurrent prolapse in the same compartment after primary surgery. This is 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". This equates to approximately 4000 cases of site specific recurrent prolapse surgery. This is the group of procedures included in this service specification.

In addition to failure of surgery for pelvic organ prolapse and/or urinary incontinence these surgeries may be followed by the following problems:

- Mesh complications (NHS England has a separate service specification for complex complications requiring intervention).
- Urinary voiding dysfunction
- Urinary incontinence
- Urinary/ Vesicovaginal fistula (NHS England has a separate service specification)
- Ano-rectal dysfunction including incontinence (NHS England has a separate service specification for colorectal incontinence issues)
- Dyspareunia

There is no single procedure that is appropriate for all situations, so treatment options should be discussed at the MDT and with the patient to determine the most appropriate option for each patient.

Combined urinary and faecal incontinence and/or combined rectal and vaginal prolapse.

Urinary and faecal incontinence and urinary and rectal prolapse are common conditions. The prevalence of faecal incontinence in women suffering with urinary incontinence is 9% to 26%. The majority of women will be treated by non-specialised services with non-surgical interventions or appropriate single compartment surgery.

In a small number of women simultaneous surgery with a gynaecologist or urologist and colorectal surgeon is required.

This will include

- Women with intractable incontinence requiring urinary or faecal diversion procedures

- Complex co-morbidities for example neurological including paraplegia, multiple sclerosis.

It is estimated that 700 such specialised procedures are performed annually.

3.3 Expected Significant Future Demographic Changes

There are no expected significant demographic changes.

3.4 Evidence Base

This specification is based on the following clinical evidence.

- NICE (2015) Urinary incontinence in women: management. CG171
- NICE (2012) Urinary incontinence in neurological disease: assessment and management. CG 148
- NICE (2004) Sacral nerve stimulation for urgency incontinence and urgency frequency. IPG64
- NICE (2017) Extra urethral (non-circumferential) retro-pubic adjustable compression devices for stress urinary incontinence in women IPG576
- NICE (2005) Intramural urethral bulking procedures for stress urinary incontinence, NICE Interventional Procedures Guidelines IPG138
- NICE (2016) Single-incision short sling insertion for stress urinary incontinence in women, IPG566
- 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 (2017) Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, IPG577
- NICE (2007) Faecal incontinence: The management of faecal incontinence in adults' CG49
- NICE (2006) Stimulated graciloplasty for faecal incontinence IPG 159
- NICE (2004) Sacral nerve stimulation for faecal incontinence IPG 99
- NICE (2004) Artificial anal Sphincter Implantation IPG 66
- NICE (2010) Stapled transanal rectal resection for obstructed defaecation syndrome IPG 351
- NICE (2003) Circular stapled haemorrhoidectomy IPG 34
- NICE (2008) Transabdominal artificial bowel sphincter implantation for faecal incontinence IPG 276
- NICE (2011) Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence IPG 393
- NICE (2011) Percutaneous tibial nerve stimulation for faecal incontinence IPG 395

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aim of Service

The service has the following aims:

1. To provide an MDT review of patients with complex urinary incontinence and prolapse where further surgical treatment is being considered.
2. To perform complex surgery as recommended by the MDT.

NHS Outcomes Framework Domains

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	

4.2 Indicators Include:

Outcome Measures

Number	Indicator	Data Source	Outcome Framework Domain	CQC Key question
Clinical Outcomes				
101	Numbers of patients referred for recurrent urinary incontinence surgery	Provider	2,3,5	effective
102	Number of patients treated for recurrent urinary incontinence	Provider	2,3,5	effective
103	Number of patients referred for recurrent prolapse	Provider	2,3,5	effective
104	Number of patients treated for recurrent prolapse	Provider	2,3,5	effective
105	Number of patients treated for removal of uncomplicated removal of vaginal mesh	Provider	2,3,5	effective
106	Number of patients return to theatre within 30 days	Provider	2,3,5	effective
107	30 day mortality	Provider	2,3,5	effective
108	Mean length of stay in hospital	Provider	2,3,5	effective

Patient Experience				
201	Patients and carers are provided with information	Self-declaration	4	caring, responsive
202	Feedback from patients is reviewed and informs service development and improvements	Self-declaration	4	caring, responsive
203	Patients discuss treatment options with multi-disciplinary team	Self-declaration	4	caring, responsive
Structure and Process				
001	There is a named clinical lead	Self-declaration	2,3,5	Well led
002	There is a specialist team	Self-declaration	2,3,5	effective, safe
003	Removal of uncomplicated vaginal mesh is undertaken by designated consultants	Self-declaration	2,3,5	effective, safe
004	There are monthly MDT treatment planning meetings	Self-declaration	2,3,5	effective, safe
005	There are clinical guidelines in place	Self-declaration	2,3,5	effective, safe
006	There are patient pathways in place	Self-declaration	2,3,5	effective, safe
007	The service is submitting data to a national database	Self-declaration	2,3,5	effective, safe

Detailed definitions of indicators, setting out how they will be measured, are included in schedule 6.

4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C

4.4 Applicable CQUIN goals are set out in Schedule 4D

5. Applicable Service Standards

Please use the following convention in each of the sections below: Mandatory standards should be set out in sentences beginning 'The provider must...'. Developmental standards should be set out in sentences beginning 'The provider should...'. Please note that these standards will be used to assess compliance, guide potential derogation and / or decommissioning.

5.1 Applicable Obligatory National Standards

Providers of this service should ensure that all current NICE and professional guidance over the intervention and treatment options to treat complex urinary incontinence and/ or vaginal or uterine prolapse

5.2 Other Applicable National Standards to be met by Commissioned Providers

Not applicable

5.3 Other Applicable Local Standards

Not applicable

6. Designated Providers (if applicable)

Please only set out a restrictive list of providers (using full trust or other full organizational names) if there has been a formal selection process which has resulted in a limited range of commissioned providers. Otherwise please mark as 'not applicable'

7. Abbreviation and Acronyms Explained

MDT Multi-disciplinary team
MRI Magnetic resonance imaging
MAG 3 Scan Mercapto acetyl tri-glycine scan
MR Magnetic resonance
STARR Stapled Transanal Resection of the Rectum
MUS Mid urethral sling procedures
BSUG The British Society of Urogynaecology
BAUS The British Association of Urological Surgeons
NICE National Institute for health and care excellence
MHRA Medicines and Healthcare Products Regulatory Agency
NRLS The National and Learning System (NRLS)
StEIS Serious Incidents to the Strategic Executive Information System
IUGA International Urogynaecological Association
ICS International Continence Society