

**A08/S/d**

**2013/14 NHS STANDARD CONTRACT  
FOR COLORECTAL: FAECAL INCONTINENCE (ADULT)**

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

<b>Service Specification No.</b>	A08/S/d
<b>Service</b>	Colorectal: Faecal Incontinence (Adult)
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	
<b>Period</b>	12 months
<b>Date of Review</b>	

**1. Population Needs**

**1.1 National/local context and evidence base**

Faecal incontinence (FI) occurs when a person loses control of their bowel and is unable to retain faeces in the rectum. Faecal incontinence may result from dysfunction of the anal sphincter as a result of sphincter damage or trauma; spinal injury; pelvic radiotherapy or a neurological disorder. Faecal incontinence is associated with a high level of physical and social disability and occurs in up to 10 % of the population at some time (with approximately 2% of the population suffering severe incontinence). Available data suggest that the standard benchmark rate for a referral into a faecal continence service is 0.1%, or 100 per 100,000, of the adult population (aged 15 years or older) per year.

Typically, first line treatment for faecal incontinence is conservative treatment in the community by GP's or specialist continence advisers utilising anti-diarrhoeal medication and habit-training techniques and coping strategies. Where a satisfactory outcome is not achieved in community services, GPs will refer on to a gastroenterologist or colorectal surgeon in secondary care where a patient would undergo investigations, including anorectal physiological testing and endo-anal ultrasound. Treatment options at this stage include biofeedback; percutaneous tibial nerve stimulation (PTNS); anal plugs; rectal irrigation and medication optimisation. Clinical consensus is that stoma formation at this stage is inappropriate.

People with disabling faecal incontinence which has failed conservative treatment, Should be referred for specialist advice. In the past 10 years significant advances

have been made in managing this group of people and they should be offered multi-disciplinary advice and treatment. Optimal outcomes are achieved when patients are seen by centres that are able to effectively consider all treatment options for faecal incontinence that has not successfully been managed with conservative approaches.

In patients for whom conservative treatments have been unsuccessful, surgical alternatives include sphincter repair (overlapping sphincteroplasty), creating a new sphincter from the patient's own muscle (dynamic graciloplasty), implanting an artificial sphincter, and sacral nerve stimulation.

In patients with a weak sphincter, it may be possible to alter the sphincter and bowel behaviour using sacral nerve stimulation. This involves applying an electric current to one of the sacral nerves via an electrode placed through the corresponding sacral foramen. Commonly this procedure is tested over a two to three week period with a temporary percutaneous peripheral nerve electrode attached to an external stimulator. If significant benefit can be achieved, then a permanent implantable pulse generator can be implanted.

Dynamic graciloplasty is an operation that augments the sphincter muscles. This is achieved by taking a muscle from the thigh and using it to create an artificial sphincter. Electrodes are inserted into this muscle, which are attached to a pulse generator placed inside the abdomen. The pulse generator runs an electrical current through the implanted muscle, which changes the way the muscle works to make it act like a natural sphincter muscle.

Bulking agents can be injected into the sphincter muscles and rectum to narrow the aperture of the sphincter muscle. The use of bulking agents in this way is a fairly new technique, so there is little information about the long-term effectiveness and safety of this type of treatment.

Endoscopic radiofrequency (heat) therapy is a new treatment for bowel incontinence. Heat energy is applied to the sphincter muscles through a thin probe, to encourage scarring of the tissue. This tightens the muscles and helps to control bowel movements.

### **Evidence base**

National Institute for Health and Clinical Excellence (NICE) Interventional Procedure Guidance IPG66 – Artificial Anal Sphincter Implantation

NICE Interventional Procedure Guidance IPG99 – Sacral Nerve Stimulation for Faecal Incontinence

NICE Interventional Procedure Guidance IPG210 – Injectable Bulking Agents for Faecal Incontinence

NICE Interventional Procedure Guidance IPG393 - Endoscopic radiofrequency

therapy of the anal sphincter for faecal incontinence

## 2. Scope

### 2.1 Aims and objectives of service

The aim is to restore faecal continence in patients, where this aim has been unsuccessful through conservative management, such that their day to day activities or quality of life are not affected.

The service will achieve this aim by:

- Providing multi-disciplinary assessment and review
- Identifying the most appropriate intervention for the individual patient
- Providing the intervention, which may include:
  - Sphincter repair surgery
  - Injection of bulking agents
  - Sacral nerve stimulation
  - Artificial sphincter implantation\*
  - Dynamic Graciloplasty
  - Endoscopic Radiofrequency Therapy\*
- Providing support to the patient and their family in living with their condition

\* - These procedures should not, at this stage, be undertaken outwith a clinical trial as there is limited evidence of efficacy to support their routine clinical use.

### 2.2 Service description/care pathway

The specialised service for faecal incontinence specialised service comprises the following elements:

- Referral of patients with faecal incontinence that is significantly affecting their activities of daily living and quality of life. This will be patient driven, once conservative measures have been tried and failed to improve symptoms and before stoma formation is considered.
- Review by a colorectal surgeon with a special interest in faecal incontinence and discussion in a multi-disciplinary meeting.
- Identification of the most appropriate treatment option, taking into account the individual needs of the patient.
- Follow-up
- Discharge

### Multi-disciplinary Team (MDT) Review

Prior to multidisciplinary team (MDT) discussion, the patient will be reviewed in an out-patient clinic by a member of the specialist MDT who will undertake a detailed history and examination; and initiate appropriate investigations. Patients will then be

discussed at the MDT and a treatment plan identified.

Patients will then be reviewed in clinic and a treatment plan finalised. At this outpatient appointment the patient will have an opportunity to discuss the pros and cons of interventions. The patient will be given written information regarding the planned procedure, the hospital stay and immediate postoperative information regarding recovery. They will be introduced to the principle surgeon and nurse specialist as the link worker with a telephone contact for the team. A summary of the discussions and management plan will be provided to the GP and be offered to the patient if they wish to have a copy.

## **Surgery**

Specialised procedures for faecal incontinence will largely be delivered as day-case procedures. Artificial sphincter implantation; sphincteroplasty; and dynamic graciloplasty procedures would be undertaken as inpatient procedures.

## **Follow-up Review**

Patients will be followed up by the specialist unit while their FI remains a problem or until there are no further treatment options available other than a stoma at which point they will exit the specialist service.

Where devices have been implanted follow up will remain with the specialist service.

Follow up clinics will be run by colorectal surgeons and appropriate technical staff. This MDT will be composed of :

- 2 colorectal surgeons with a special interest in faecal incontinence. Specialist nurse with interest in FI
- Ano-rectal physiological testing and endoscopic anal ultrasound
- Physiologist / nurse who is responsible for following up patients who have undergone SNS implantation
- Radiologist with interest to pelvic floor imaging able to perform MR-def or def. proctogram
- Urogynaecology and gastroenterology support
- Access to psychological support.

## **Access and exit to service**

Referral by a colorectal surgeon or gastroenterologist with an interest in faecal incontinence to the specialist service and not to a named consultant.

Patients will remain under the care of the specialised service until:

- The specialist unit deem no surgical intervention is appropriate and the patient is referred back to the local service or onto another service.
- Surgical intervention has been undertaken. Then patients will be discharged

back to local services. This will ordinarily be at the first outpatient attendance

following discharge from the inpatient surgical spell. However patients who have undergone nerve stimulation implantation require patient led follow up re programming of their unit. This needs to be performed by a member of the specialist team. Patients require telephone access to a member of the specialist team.

- They become ineligible for NHS funded care or they die whilst undergoing treatment.
- They elect to discontinue receiving care provided by the service.

### 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:

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/ :.DH\\_127393](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/ :.DH_127393)

(\*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 adults with faecal incontinence that has failed to be managed using conservative treatment options.

### 2.4 Any acceptance and exclusion criteria

The criteria for referral shall be:

- Failure of conservative treatment for faecal incontinence
- Percutaneous tibial nerve stimulation and/or specialist nurse-led behavioural techniques (habit training; biofeedback techniques; anal irrigation systems) have been tried and have not yielded adequate bowel continence. (These techniques are outside the scope of the specialised service and these options should be exhausted prior to referral).
- Patient has been reviewed by a colorectal surgeon or gastroenterologist and, as a minimum, a flexible sigmoidoscopy has ruled out hind gut disease. Where available, the result of an endo-anal ultrasound and anorectal physiology tests should support the referral to the specialised service.

## 2.5 Interdependencies with other services

### Co-located services

Services which must be provided from the same healthcare setting (i.e. the same hospital site) as the specified service are as follows:

Services

- Full general medical services
- Gastroenterology services
- Stoma therapy services

### Interdependent services

Services which the specified service will require access to routinely, for care provided during the period of the pathway described in this specification, but for which there is no absolute requirement for these services to be physically co-located on the same healthcare delivery site are:

- Uro-gynaecology, urology and gastroenterology services
- Sexual dysfunction services
- Community continence services.

### Related services

The service forms part of a pathway of care provided in a number of settings by different providers. The service will need to maintain excellent communication with other agencies and services providing care to the patient including their General Practitioner and secondary care Cancer Centre who will be responsible for the longer-term follow-up of patients treated by this service.

## 3. Applicable Service Standards

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

NICE Interventional Procedure Guidance IPG66 – Artificial Anal Sphincter Implantation.

NICE Interventional Procedure Guidance IPG99 – Sacral Nerve Stimulation for Faecal Incontinence.

NICE Interventional Procedure Guidance IPG210 – Injectable Bulking Agents for Faecal Incontinence.

NICE Interventional Procedure Guidance IPG393 - Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence.

Centers should undertake the following minimum volumes of activity to

maintain competence:

- MDT should discuss a minimum of 50 new referrals per year.

#### 4. Key Service Outcomes

Collection of outcome data and use of National Pelvic floor data base.

Interim for adoption from 01/10/13